

EXHIBIT 82

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**UNITED STATES DISTRICT COURT
DISTRICT OF KANSAS**

IN RE: EPIPEN (EPINEPHRINE INJECTION,
USP) MARKETING, SALES PRACTICES,
AND ANTITRUST LITIGATION

Civil Action No. 2:17-md-02785-DDC-TJJ
(MDL No: 2785)

THIS DOCUMENT RELATES TO:
CONSUMER CLASS CASES

EXPERT REPORT OF JAMES W. HUGHES

I. QUALIFICATIONS

1. I am the Thomas Sowell Professor of Economics at Bates College. I specialize in the fields of health economics, industrial organization, law and economics, and labor economics. I earned my M.A. in Economics from Boston University in 1978 and my Ph.D. in Economics from the University of Michigan in 1987. I joined the faculty of Amherst College in 1987 and the faculty of Bates College in 1992. In 2005, I was named the Thomas Sowell Professor of Economics.

2. I studied health economics, including pharmaceuticals, at the University of Michigan, and have since taught a health economics course on several occasions. I began my professional work on the pharmaceutical industry when I served as a consulting economist on the Brand Name Prescription Drugs Antitrust Litigation¹ in 1995, the Warfarin Sodium Antitrust Litigation² and Cardizem CD Antitrust Litigation³ in 1998 and 1999. Due to the nature of the allegations, I was required to examine every facet of the pharmaceutical distribution and payment systems. In 1998, I began working as a testifying expert, and have since testified in over thirty cases involving various aspects of the pharmaceutical marketplace. The courts accepted my testimony in each of these thirty cases.

3. I have extensive experience in the economic analysis of class certification issues in the pharmaceutical industry. I have testified and/or offered reports in such matters involving the prescription drugs Celexa®, Lexapro®, Cipro®, Cardizem CD®, Intuniv, Lamictal®,

¹ *In re Brand Name Prescription Drugs Antitrust Litigation* Nos. 94 C 897, MDL 997 (N.D. Ill.)

² *In re Warfarin Sodium Antitrust Litigation*, No. MDL 98-1232-SLR (D. Del.)

³ *In re Cardizem CD Antitrust Litigation*, No. 99-md-1278 (E.D. Mich.)

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Lidoderm®, Loestrin®, Neurontin®, Nexium®, Niaspan®, Rezulin®, Procardia XL®, Provigil®, Skelaxin®, and Thalomid® and Revlimid®.⁴ I have provided deposition testimony at the class certification stage during antitrust litigation involving claims against pharmacy benefit manager Medco Health Solutions.⁵ I also have experience in the analysis of injury and damages issues relating to pharmaceutical pricing in the Average Wholesale Price (“AWP”) litigation in the States of Connecticut, Montana, and Nevada, as well as relator cases in Alabama and Florida.⁶

4. My curriculum vitae and a list of my prior testimony in the past four years are attached as Appendices A and B, respectively. My curriculum vitae includes a list of all of my publications from the last ten years.

5. I am being compensated at my standard billing rate of \$950 per hour. I have been assisted in this matter by staff of Compass Lexecon, who worked under my direction. My

⁴ *Celexa and Lexapro Marketing and Sales Practices Litigation*, Master Docket No. 09-MD-02067-(NMG) (D. Mass.); *Altman v. Bayer Corp.*, Index No. 603820-00 (N.Y. Sup. Ct.); *Cipro Cases I & II*, JCCP Proceeding Nos.: 4154 & 4220 (Cal. Super., San Diego County); *In Re Cardizem CD Antitrust Litigation*, *Blue Cross Blue Shield of Michigan, et al. v. Hoechst AG, et al.*, Case No. 01-72806 (E.D. Mich.); *In re: Intuniv Antitrust Litigation*, Lead case no. 1:16-cv-12396-ADB (D. Mass.); *In re Lamictal Direct Purchaser Antitrust Litigation*, Case No. 12-cv-995 (WHW) (D.N.J.); *In re: Lidoderm Antitrust Litigation*, MDL Docket No. 14-md-02521-WHO (N.D. Cal.); *In re: Loestrin 24 Antitrust Litigation*, MDL No. 2472 (D.R.I.); *In Re: Neurontin Antitrust Litigation*, *Louisiana Wholesale Drug Company et al., v. Pfizer Inc., et al.* MDL Docket No. 1479, Master Docket No. 02-CV-1390 (D.N.J.); *In Re: Nexium (esomeprazole) Antitrust Litigation*, MDL 2409, Civil Action No.: 1:12-md-2409-WGY (D. Mass.); *Holoman, et al. v. Pfizer Inc., et al.*, No. 02 L 480 (Ill. Cir. Ct.); *Great Lakes Health Plan et al. v. Pfizer, et al.*, No. 1:01CV106 (N.D. W.Va.); *King Drug Company of Florence Inc. et al., v. Cephalon Inc. et al.*, No. 2:06-cv-1797 (E.D. Pa.); *In Re: Skelaxin (metaxalone) Antitrust Litigation*, Lead Case No. 2:12-cv-4, MDL 2343 (E.D. Tenn.); *In re Thalomid and Revlimid Antitrust Litigation*, Case No. 2:14-cv-06997 (MCA) (MAH) (D.N.J.); *In re Niaspan Antitrust Litigation*, Case No. 2:13-md-2460 (E.D. Pa.).

⁵ *Brady Enterprises, et al. v. Medco Health Solutions, et al.*, Civ. No. 03-4730 (E.D. Pa.).

⁶ *State of Alabama v. Abbott Laboratories Inc. et al.*, Civil Action CV 2005-219 (Ala. Cir. Ct.); *State of Connecticut v. Aventis Pharmaceuticals*, Docket X07 CV03-0083299 S (CLD); *In Re: Pharmaceutical Industry Average Wholesale Price Litigation*, in the matters of *State of Nevada v. American Home Prods. Corp., et al.*, 02-CV-12086-PBS (D. Mass.); *State of Montana v. Abbott Labs., Inc., et al.*, 02-CV-12084-PBS, MDL No. 1456, Master File No. 01-CV-12257-PBS (D. Mass.); *U.S. ex rel Ven-A-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc.*, Civil Action No. 00 CV 10698 MEL (D. Mass.); *In Re Pharmaceutical Industry Average Wholesale Price Litigation*, *In the matter of United States of America ex rel. Ven-a-Care of the Florida Keys, Inc., v. Abbott Laboratories, Inc.*, Civil Action No. 06-11337-PBS (D. Mass.).

compensation in this matter is in no way contingent or based on the content of my opinion or the outcome of this or any other matter. The materials I considered in developing my opinions are attached as Appendix C. I reserve the right to supplement or amend this report and the opinions contained herein based on additional discovery, data, or other events in the litigation.

II. BACKGROUND

A. Assignment

6. I have been retained by the law firm Hogan Lovells US LLP for the purpose of providing expert testimony to assist the Court in connection with its assessment of Class Plaintiffs' Motion for Class Certification.

7. In particular, in order to assist the Court in understanding the commercial context of this case, I have been asked to provide in this report an explanation of the flow of products and payments in the prescription drug space and the roles that various actors, including third-party payors, pharmacy benefit managers ("PBMs"), and consumers, play in the pharmaceutical supply and payment chain.

8. I also have been asked to analyze whether the classes as defined by Class Plaintiffs in their Motion for Class Certification are presently ascertainable such that members of the classes can be identified. In particular, I have been asked to determine whether (1) Class Plaintiffs have proposed any methodology for analyzing data so as to determine which consumers are part of the classes as defined and which are not, and (2) whether the data produced in this case include information sufficient to perform this task.

B. Plaintiffs' Allegations

9. In their operative complaint, Class Plaintiffs allege that Mylan, Pfizer, Inc., King Pharmaceuticals, and Meridian Medical Technologies, Inc. ("Defendants") "devised an illegal

scheme to monopolize the market for epinephrine auto-injector devices.”⁷ Class Plaintiffs claim that, in furtherance of this scheme, the Defendants undertook a variety of illegal actions that collectively resulted in patients paying higher prices for epinephrine auto-injector (“EAI”) devices.⁸ In their most recent filing, Class Plaintiffs have classified these allegedly illegal actions into three main groups:⁹

- Entering into “anticompetitive settlements to delay entry of generic competition”;
- Entering into “exclusive agreements and contracts with [PBMs], facilitated by kickbacks”; and
- Requiring patients to purchase EpiPen® (“EpiPen”) Auto-Injectors in packages of two devices by eliminating single-packs.

Plaintiffs claim that, because of Defendants’ alleged conduct, “all Class members were overcharged and oversold for EpiPens.”¹⁰

C. Class Definitions

10. I understand the Plaintiffs are seeking to certify five classes:¹¹

1. Nationwide Injunctive Relief Class (“Injunctive Class”)

All persons and entities in the United States who paid or provided reimbursement for some or all of the purchase price of Branded or AB-rated generic EpiPens for the purpose of consumption, and not resale, by themselves, their family member(s), insureds, plan participants, employees, or beneficiaries, at any time from August 24, 2011, until the effects of Defendants’ unlawful conduct cease.

2. Nationwide RICO Damages Class (“RICO Class”)

The proposed nationwide RICO Class is coterminous with the Injunctive Class.

⁷ Consolidated Class Action Compl. ¶ 4, October 17, 2017 (“Complaint”).

⁸ *Id.* at ¶ 148.

⁹ Class Pls.’ Mem. of Law in Supp. of Mot. for Class Certification 1–2, December 7, 2018 (“Plaintiffs’ MOL”).

¹⁰ *Id.* at 2.

¹¹ *Id.* at 27-28.

3. State Antitrust Damages Class (“State Antitrust Class”)

All persons and entities in the Antitrust States¹² who paid or provided reimbursement for some or all of the purchase price of Branded EpiPens at any time from January 28, 2013, until the effects of Defendants’ unlawful conduct cease, for the purpose of consumption, and not resale, by themselves, their family member(s), insureds, plan participants, employees, or beneficiaries.

4. Consumer Protection Damages Class (“CP Class”)

All persons and entities in the Consumer Protection States¹³ who paid or provided reimbursement for some or all of the purchase price of Branded EpiPens at any time from August 24, 2011, until the effects of Defendants’ unlawful conduct cease, for the purpose of consumption, and not resale, by themselves, their family member(s), insureds, plan participants, employees, or beneficiaries.

5. Unjust Enrichment Class (“UE Class”)

All persons and entities in the Unjust Enrichment States¹⁴ who paid or provided reimbursement for some or all of the purchase price of Branded or AB-rated generic EpiPens for the purpose of consumption, and not resale, by themselves, their family member(s), insureds, plan participants, employees, or beneficiaries, at any time from August 24, 2011, until the effects of Defendants’ unlawful conduct cease.

11. I also understand that the Plaintiffs propose the following exclusions:¹⁵

- (a) Defendants and their officers, directors, management, employees, subsidiaries, and affiliates;
- (b) Government entities, other than government-funded employee benefit plans;
- (c) Fully-insured health plans (*i.e.*, plans that purchased insurance that covered 100% of the plan’s reimbursement obligations to all of its

¹² The “Antitrust States” are: Alabama; Arizona; California; District of Columbia; Florida; Hawaii; Illinois; Iowa; Kansas; Maine; Michigan; Minnesota; Mississippi; Nebraska; Nevada; New Hampshire; New Mexico; New York; North Carolina; North Dakota; Oregon; Rhode Island; South Dakota; Tennessee; Utah; Vermont; West Virginia; and Wisconsin.

¹³ The “Consumer Protection States” are: Alaska; California; Connecticut; District of Columbia; Florida; Hawaii; Illinois; Maine; Maryland; Massachusetts; Missouri; Nebraska; Nevada; New Hampshire; New Mexico; North Carolina; Oklahoma; Rhode Island; Vermont; Washington; and West Virginia.

¹⁴ As discussed below, all 50 states are “Unjust Enrichment States.” If one of the other remedies eventually provides a remedy at law, Arizona, Delaware, Louisiana, and North Dakota will be excluded from this class at that time.

¹⁵ Plaintiffs’ MOL at 28-29.

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members);

- (d) “Single flat co-pay” consumers who purchased EpiPens or generic EpiPens only via a fixed dollar co-payment that is the same for all covered devices, whether branded or generic (*e.g.*, \$20 for all branded and generic devices);
- (e) Consumers who purchased or received EpiPens or AB-rated generic equivalents through a Medicaid program only;
- (f) All persons or entities who purchased branded or generic EpiPens directly from Defendants; and
- (g) The Judges in this case and members of their immediate families.

III. SUMMARY

12. In section IV below, I provide an overview and explanation of the economic and commercial context surrounding the distribution of and payment for prescription drugs in the United States. Among other things, I explain and illustrate the roles of drug manufacturers, wholesalers, pharmacies, health plans, health insurers, and pharmacy benefit managers. I also discuss particular third-party payors, including named Plaintiff Local 282, to help illuminate the diversity of payors and the complexity of commercial arrangements relating to prescription drugs in the United States.

13. In section V below, I provide my opinion relating to ascertainability. As I explain in that section, determining who is included and excluded from a proposed class is a fundamental issue in class action litigation. I have examined in detail much of the data provided in discovery in this matter, covering millions of lives and transactions. Based on that analysis, and my knowledge and expertise in the pharmaceutical industry, I do not believe that the basic task of identifying who is included or excluded from the class may be done with these data.¹⁶

¹⁶ Data I have examined include: Aetna00019823.xlsx (Aetna data); ANTH-EPI 03619.XLSB, ANTH-EPI 03620.XLSB, ANTH-EPI 03621.XLSB, and ANTH-EPI 03622.XLSB (Anthem data); BCEPI000216.xlsx and

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14. Specifically, I have reviewed data and documents that have been provided in discovery in this matter and conclude that they are insufficient to identify putative class members, as the data do not contain personal information, and they are insufficient to (a) include all the relevant class members, with cash customers being a substantial missing group, and (b) exclude individuals from the class who did not actually pay for an EpiPen device.

15. The data also do not contain information sufficient to identify whether a particular claimant has a “single flat copay” as part of his or her benefit plan. Claimants with single flat copays fall outside the class definition, but Plaintiffs have not proposed any means of excluding them.

16. Thus, based on the data and other materials I have reviewed, the Plaintiffs do not provide data or a methodology for identifying which individuals should be excluded and included in the class.

IV. ECONOMICS OF PRESCRIPTION DRUGS IN THE UNITED STATES

17. The system that exists in the United States for supplying pharmaceutical products is complex and multifaceted. Below I describe key economic features of the U.S. pharmaceutical supply and payment chains to facilitate the assessment of Class Plaintiffs’ allegations and evidence in their proper economic context. In particular, I describe the flow of prescription drug

BCEPI000217.xlsx (Blue Cross Blue Shield of Arizona data); ARBCBS00000001.txt (Blue Cross Blue Shield of Arkansas data); BCEPI000216.xlsx and BCEPI000217.xlsx (Blue Cross Blue Shield of Arizona data); ARBCBS00000001.txt (Blue Cross Blue Shield of Arkansas data); BCBS-MA00003073.xlsb (Blue Cross Blue Shield of Massachusetts data); BS-CA0003518_001.xls (Blue Shield of California data); CAREFIRST_MDL02785_001650.xls (CareFirst data); CVSCM_EPIDATA_00001.txt (CVS data); ES_0000017.txt and ES_0000018.txt (Express Scripts data); Horizon00013639.xlsx (Horizon data); HUM000002.xlsx (Humana data); EAI 00243753.xlsx to EAI 00243755.xlsx, EAI 00243984.xlsx to EAI 00243988.xlsx, EAI0243989.xlsx to EAI0244013.xlsx (Optum data); HPHC000001 - CONFIDENTIAL - Copy of Copy of HPH_EpiPens_2007_2011_PHI_Redacted.XLSX, HPHC000002.XLSX, and HPHC000003.XLSX (Harvard Pilgrim Health Care); and Coupons 01.16 – 08.16 (HIGHLY CONFIDENTIAL).xlsx, Coupons 07.15 - 12.15 (HIGHLY CONFIDENTIAL).xlsx and Coupons 02.13-06.15 (HIGHLY CONFIDENTIAL).xlsx (Mylan coupon data).

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products and payments in the U.S., along with the various participants, including consumers, insurers, PBMs, plan sponsors, health insurers, pharmacies, wholesalers and manufacturers.

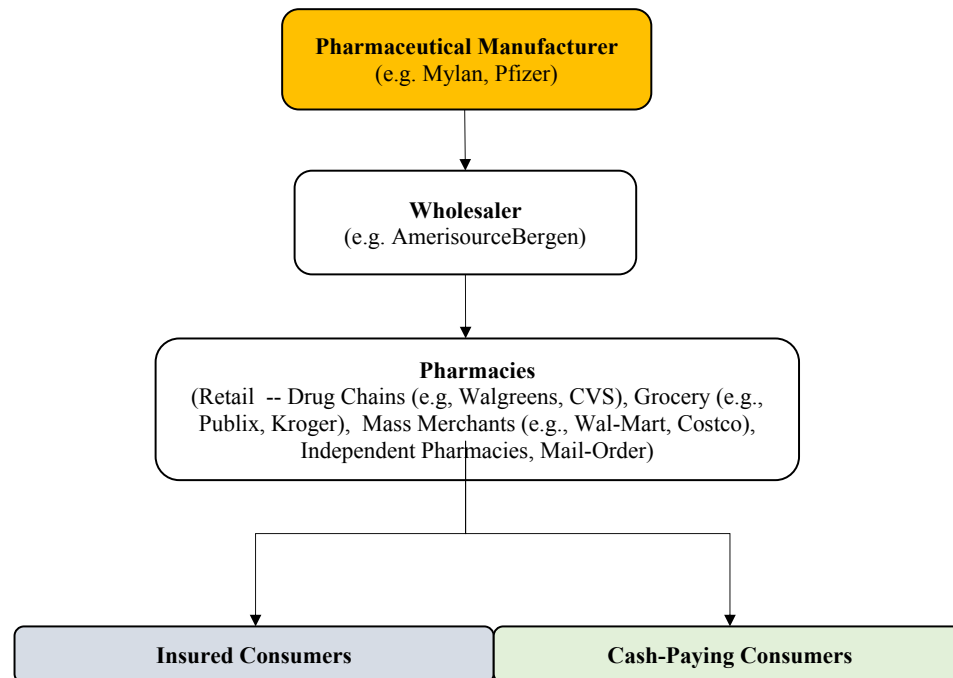
18. As discussed in the sections that follow, the journey of a pharmaceutical product from the manufacturer to the consumer, as well as the payment for that product, involves several entities. Because of complex contract terms that vary across plans and over time, the journey of any two prescriptions and their payments are rarely the same.

A. Pharmaceutical Product Flow

19. In this section, I describe the flow of products from manufacturer to consumer, along with an indication of pricing and terms along the various stages of distribution. Figure 1 provides an illustration of the pharmaceutical product flows.

Figure 1

Overview of Product Flow for Branded Products in Pharmaceutical Supply Chain



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20. First, the manufacturer sells its product to a wholesaler. Examples of drug wholesalers include AmerisourceBergen and McKesson. The wholesalers are responsible for transporting the product from the manufacturer and distributing it to the more than 60,000 pharmacies across the country. The price wholesalers pay to the manufacturer is known as the Wholesale Acquisition Cost or “WAC.” WAC is the manufacturer’s list price for the pharmaceutical products sold to wholesalers or direct purchasers but does not include discounts or rebates.

21. Next, the wholesaler sells the pharmaceutical product to the pharmacy. The price of this transaction is a subject of negotiation between the wholesaler and the pharmacy and is generally specified in individually negotiated contracts. The price paid by the pharmacy generally does not take into account any discounts or rebates that may be due to the pharmacy from the manufacturer or wholesaler.

22. Often, the wholesaler will buy pharmaceuticals from the manufacturer under the terms of one contract but sell them to the pharmacy at a lower price under the terms of a different contract, granting price concessions to the pharmacy due to discounts or rebates. In such situations, the wholesaler processes a “chargeback,” whereby the manufacturer makes up the difference to the wholesaler between the higher price paid to the manufacturer and the lower price the wholesaler received from its pharmacy customers.

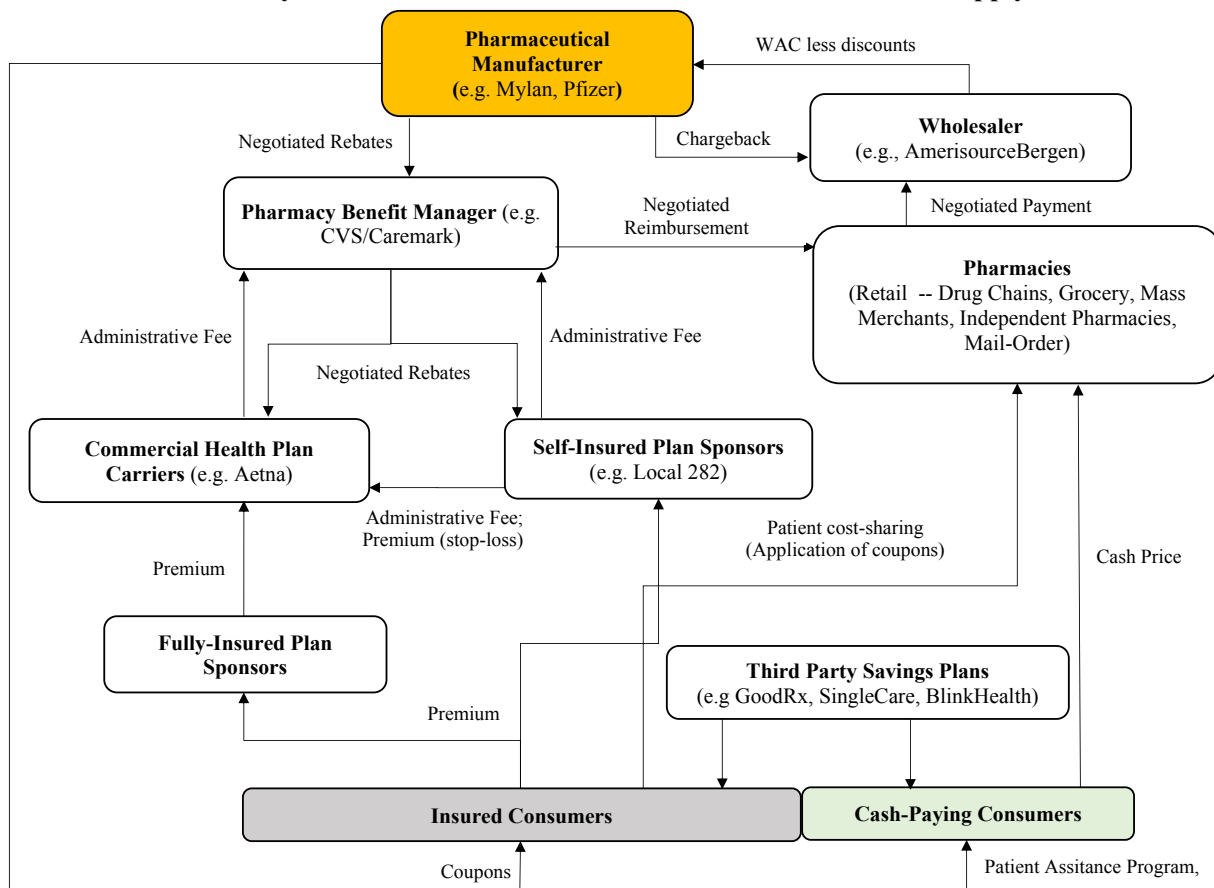
B. Pharmaceutical Payment Flows

23. Most prescription payment flows are highly complex. Figure 2 below provides an illustration of the possible payment flows for an insured consumer.

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Figure 2

Overview of Payment Flow for Branded Products in Pharmaceutical Supply Chain



24. Prescription drug payment flows depend on a number of individualized factors, starting with whether the patient has health insurance that covers prescription drugs. In the following sub-sections, I discuss the payments made by consumers and also by third-party payors (“TPPs”).

i. Payments Made by Consumers

25. A consumer without prescription drug coverage (called a “cash payor”) pays the pharmacy for the drug. The pharmacy sets its “Usual & Customary” (“U&C”) or “cash” price

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that is charged to customers without health insurance.¹⁷ The manufacturer has no control over this price set by the pharmacy. Pricing practices vary across pharmacies and over time. For example, pharmacies may adjust their pricing strategy to meet local competition or for promotional reasons such as creating “loss leaders.”¹⁸

26. Cash customers do not always pay the pharmacy U&C cash price. Promotions from drug manufacturers, usually brand drug manufacturers, like free samples,¹⁹ discount coupons, copayment coupons and prescription assistance plans, often reduce the price consumers pay for a brand name drug below the pharmacy U&C price. Third party programs such as GoodRx,²⁰ BlinkHealth²¹ or SingleCare²² provide discounted cash drug prices to consumers, again reducing the cash paying consumer’s expenditure below the stated pharmacy U&C price.

27. A consumer with prescription drug coverage (called an “insured customer”) is in a different situation than a cash customer, and the prices that these consumers pay for drugs also vary significantly from pharmacy to pharmacy and over time. Because different insurance plans provide a wide variety of prescription drug benefits (e.g., in determining which drugs are

¹⁷ Joey Mattingly, *Understanding Drug Pricing*, U.S. PHARMACIST tbl. 1 (June 2, 2012), <https://www.uspharmacist.com/article/understanding-drug-pricing>.

¹⁸ Tori Marsh, *What Happened to \$4 Generics?*, GOODRX BLOG, (Jan. 15, 2019), <https://www.goodrx.com/blog/what-happened-to-4-generics/>.

¹⁹ See, e.g., Henry Grabowski et al., *Does Generic Entry Always Increase Consume Welfare?*, 67(3) FOOD & DRUG L.J., 373, 374 (2012) (“In particular, generic competition reduces the incentives of brand manufacturers to inform physicians about the benefits of their drugs, provide price discounts in the form of free samples, and to enhance the usefulness of their drugs by seeking approval for additional indications.”); *id.* at 379 (“Free samples also affect the total cost of branded drugs. For example, a consumer who receives a 10 day supply or free samples and whose course or treatment lasts thirty days effectively saves one third of the expenditures on the drug.”); *id.* at 381 (“[Brand manufacturers] also compete on price by providing free samples to patients via their physicians.”).

²⁰ *How GoodRx Works*, GOODRX, <https://www.goodrx.com/how-goodrx-works> (last visited Mar. 16, 2019).

²¹ *How Blink Works*, BLINK HEALTH, <https://www.blinkhealth.com/how-blink-works> (last visited Mar. 16, 2019).

²² *SingleCare Makes Healthy Choices More Affordable*, SINGLECARE, <https://www.singlecare.com/about-us> (last visited Mar. 16, 2019).

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covered, and in determining what portion of the drug cost the consumer will bear), consumers can pay very different prices for the same drug depending on the terms of their plans.²³

Moreover, even the same insured consumer can pay very different amounts for the same drug at different points in a calendar year and different amounts in different years, depending on her other drug expenses, whether the drug benefits of her plan change, and whether she changes her plan from year to year (for example, due to working for a different employer).

28. At the beginning of a calendar year or benefit accumulation period, a consumer with a deductible that applies to prescription drug coverage generally will pay the entire cost of pharmaceutical products out-of-pocket until her deductible is met.²⁴ After the deductible is met (or if there is a \$0 deductible), the consumer only pays a portion of the cost of the prescription out-of-pocket. Depending on the plan, this is either a fixed-dollar contribution (“copayment”) or a percentage of the total amount paid to the pharmacy (“coinsurance”). The size of the copayment or coinsurance required can vary substantially across plans, as well as over time within a given plan.

29. The named plaintiffs in this case illustrate how copayments and coinsurance vary widely across individuals. Some named plaintiffs, like Plaintiff Ipson, paid \$0 copays for their EpiPen purchases.²⁵ At least one named plaintiff, Plaintiff Harwood, paid \$130 copays.²⁶ And other

²³ KAISER FAMILY FOUNDATION, FOLLOW THE PILL: UNDERSTANDING THE U.S. COMMERCIAL PHARMACEUTICAL SUPPLY CHAIN 24 (2005), <https://www.kff.org/other/report/follow-the-pill-understanding-the-u-s/> (“The pricing of prescription drugs and the flow of money among the various links in the pharmaceutical supply chain is more complex than the physical distribution of drugs through the chain. This complexity can result in substantial variations in what different purchasers pay for the same drugs. As we have shown, the price of prescription drugs paid by the consumer is determined by a constellation of negotiated contracts between manufacturers, PBMs, wholesale distributors, pharmacies, and plan sponsors.”).

²⁴ A deductible is the amount a consumer pays for covered healthcare services before their insurance plan starts to pay. *Deductible*, HEALTHCARE.GOV, <https://www.healthcare.gov/glossary/deductible/> (last visited Mar. 18, 2019).

²⁵ Ipson Dep. at 59:22-24.

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plaintiffs paid a range of amounts in between. Some named plaintiffs, like Plaintiff Sutorik, paid the same copay regardless of whether they bought one 2-Pak or multiple 2-Paks,²⁷ whereas other named plaintiffs paid separate copays for each 2-Pak purchase.²⁸ For other named plaintiffs, the amount paid out of pocket was a coinsurance percentage of the total drug price rather than a flat amount.²⁹ Some of those who had a coinsurance percentage had a cap.³⁰

30. Many health plans have out-of-pocket (“OOP”) maximums for prescription drug spending. OOP maximums set upward limits on the amount that a consumer can have to pay for prescription drugs during a benefit year. For example, in 2017, 38 percent of U.S. employers offered plans with OOP limits for prescription drug expenditures.³¹ Some plans have a single OOP maximum for prescription drugs and medical spending combined. The OOP maximum could be calculated separately for each insured consumer or based on the total drug spending incurred by all family members covered under the health plan. For example, in 2017, the average OOP maximum was \$2,635 for single consumers and \$5,399 for families.³² If a consumer or a family reaches its plan’s annual OOP maximum, the plan sponsor or health insurer covers 100 percent of drug costs after that point. However, the amount covered by the plan sponsor or health insurer after an individual or a family reaches its OOP maximum may also be limited—some plans have annual or lifetime benefit maximums. If a consumer’s or her family’s

²⁶ Harwood Dep. at 59:2-15.

²⁷ Sutorik Dep. at 164:3-13.

²⁸ *See, e.g.* Huston Dep. at 132:12-25.

²⁹ *See* Wemple Dep. at 130:17-131:2 (20 percent copay after hitting annual deductible).

³⁰ *See* Evans Dep. at 97:15-17 (20 percent copay, \$75 max).

³¹ PBMI, 2017 TRENDS IN DRUG BENEFIT DESIGN 30 (2017).

³² *Id.* at 59.

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drug costs reach those amounts, the consumer must then pay the full amount of any drug costs exceeding these maximums.

31. In addition, some consumers utilize health savings accounts (“HSAs”) to pay for some portion of their medical and pharmaceutical expenses. These may be funded by employers entirely, by individual member contributions, or by both. As of January 2017, 21.8 million people in the United States were enrolled in HSAs of all types. Of these, 14.7 million were enrolled in employer-sponsored HSAs.³³

ii. Payments Made by Third-Party Payors

32. Insured consumers generally share the total cost of prescription drugs paid to pharmacies with a TPP. TPPs include organizations such as plan sponsors, health insurers, and PBMs. I briefly describe each of these types of organizations below.

33. **Plan sponsors.** A plan sponsor is an employer, a union, or another type of employee or membership organization that makes health benefits available to its members or employees, as well as their families. Health insurance for individuals is generally organized through such plan sponsors to form larger risk pools. In 2016, the majority (56 percent) of Americans under the age of 65 received health insurance coverage as an employee benefit.³⁴ Plan sponsors may organize their health plans as fully-insured, self-insured, or a hybrid of the two, as discussed in paragraph 43 below.

³³ AMERICA’S HEALTH INSURANCE PLANS, HEALTH SAVINGS ACCOUNTS AND CONSUMER-DIRECTED HEALTH PLANS GROW AS VALUABLE FINANCIAL PLANNING TOOLS 9, App. B (2018), https://www.ahip.org/wp-content/uploads/2018/04/HSA_Report_4.12.18-1.pdf.

³⁴ *Health Insurance Coverage of Nonelderly 0-64*, KAISER FAMILY FOUNDATION, <https://www.kff.org/other/state-indicator/nonelderly-0-64/> (last visited July 20, 2018).

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34. **Health insurers.** A health insurer is another type of TPP that markets and sells health insurance services, including prescription drug coverage, to individuals, either directly or through a plan sponsor.³⁵ As of 2016, 67.5 percent of Americans used private health insurers.³⁶ A leading trade association for the health insurance industry estimates it had approximately 1,300 members that provided health insurance coverage to more than 150 million Americans with employee-based insurance coverage in 2017.³⁷ Nearly 90 percent of the nonelderly population in the U.S. has prescription drug coverage,³⁸ with private health insurers contributing 43 percent of the total national health spending on prescription drugs in 2016, making them the largest contributor to drug spending.³⁹ When a plan sponsor chooses to self-insure, it usually still hires a health insurer to administer its health plan in an administrative-services-only (“ASO”) capacity. Health insurers in this role typically handle claims processing and membership enrollment.⁴⁰ When a plan sponsor chooses to have a fully-insured contract with a health insurer,

³⁵ For the purposes of this report, I only consider commercial health insurers as distinguished from public health benefit providers such as Medicare and Medicaid.

³⁶ Jessica C. Barnett and Edward R. Berchick, *Health Insurance Coverage in the United States: 2016*, U.S. CENSUS BUREAU (Sept. 12, 2017), <https://www.census.gov/library/publications/2017/demo/p60-260.html>.

³⁷ *Membership*, AMERICA’S HEALTH INSURANCE PLANS, <https://web.archive.org/web/20150317224107/http://www.ahip.org:80/> (last visited Mar. 18, 2019); *see also America’s Health Insurance Plans (AHIP)*, AMERICA’S HEALTH INSURANCE PLANS, <http://www.aha.org/content/00-10/0704-uhp-ahip.pdf> (last visited Aug. 14, 2018).

³⁸ About 90 percent of the nonelderly population in the United States had health insurance in 2016, and the vast majority of insured workers also had prescription drug coverage. *See Health Insurance Coverage of Nonelderly 0-64*, KAISER FAMILY FOUNDATION, <https://www.kff.org/other/state-indicator/nonelderly-0-64/> (last visited July 20, 2018); KAISER FAMILY FOUNDATION, EMPLOYER HEALTH BENEFITS 2017 ANNUAL SURVEY 148 (2017).

³⁹ Rabah Kamal and Cynthia Cox, *What Are the Recent and Forecasted Trends in Prescription Drug Spending?*, PETERSON-KAISER HEALTH SYSTEM TRACKER (Feb. 20, 2019), <https://www.healthsystemtracker.org/chart-collection/recent-forecasted-trends-prescription-drug-spending/>.

⁴⁰ Bluhm, W. F., “Experience Rating and Funding Methods,” in William F. Bluhm, et al., *Group Insurance*, Fifth Edition, Chapter 35: (hereafter “Bluhm”), p. 747.

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the health insurer is responsible for all of the covered healthcare expenditures, including drug expenditures, of the plan sponsor's insured members.

35. **Pharmacy Benefit Managers (PBMs).** PBMs are entities that assist plan sponsors and health insurers with their provision of prescription benefits to insureds, including managing prescription drug costs. In particular, PBMs negotiate with pharmacies for inclusion in the PBMs' pharmacy networks—the networks of pharmacies that the insured members of a plan sponsor or a health insurer must use to obtain their prescriptions. In exchange for inclusion in the network and access to the plan sponsor's or the health insurer's members, pharmacies agree to reduced negotiated rates for the prescriptions they fill.⁴¹ PBMs reimburse pharmacies at these negotiated rates, minus any payment made by the insured consumer. PBMs then may seek reimbursement from the health insurer or plan sponsor.⁴² PBMs also negotiate rebate agreements with pharmaceutical manufacturers. The terms of those rebates are set forth in agreements between PBMs and the pharmaceutical manufacturers.⁴³

36. PBMs also develop drug formularies for health insurers and for plan sponsors. Formularies are lists of drugs covered by a particular health insurance plan.⁴⁴ Formularies generally list drugs according to different therapeutic categories, and they may have different “tiers” for particular categories. Patients' copayment or coinsurance obligations may vary

⁴¹ John M. Brooks et al., *Retail Pharmacy Market Structure and Performance*, 45 INQUIRY 75, 83-84 (2008).

⁴² Ernst R. Berndt & Joseph P. Newhouse, *Pricing and Reimbursement in U.S. Pharmaceutical Markets*, in THE OXFORD HANDBOOK OF THE ECONOMICS OF THE BIOPHARMACEUTICAL INDUSTRY 219 (Patricia M. Danzon and Sean Nicholson eds., 2012). *See also* 12 SHEILA R. SHULMAN ET AL., PBMS: RESHAPING THE PHARMACEUTICAL DISTRIBUTION NETWORK 33 (Hawthorn Press, 1998).

⁴³ PBMI, 2017 TRENDS IN DRUG BENEFIT DESIGN 20 (2017).

⁴⁴ *Id.* at 24.

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according to which tier a product occupies on the formulary.⁴⁵ In addition, some drugs may be excluded from formularies altogether or subject to particular restrictions, including “prior authorizations” or “step therapy” requirements.⁴⁶

37. As discussed in paragraphs 50 to 62 below, the lines between PBMs and health insurers are not always clear. Some health insurers, for example, have their own PBMs or otherwise perform for themselves the same tasks that PBMs often undertake. These include negotiating rebates with drug manufacturers and establishing formularies.

iii. The Flow of Payments Made by TPPs

38. The net amount paid for a prescription drug by each participant in the payment chain is typically governed by complex and individualized contractual arrangements. In addition to the consumer’s payment (in the form of a copayment or coinsurance), when a consumer has insurance, pharmacy reimbursement usually is paid either directly by the consumer’s health insurer, or by the pharmacy benefit manager hired by the health insurer or health plan to administer its pharmacy benefit. The reimbursement from the insurer or PBM to the pharmacy is governed by contracts negotiated between the pharmacy and the PBM or insurer. These individually negotiated contracts mean that different prescription drug plans have different pharmacy reimbursement rates, largely dependent on the restrictiveness of the plan formulary. A single pharmacy will have many different reimbursement rates from different prescription drug plans and different PBMs. In addition, these reimbursement rates change over time as

⁴⁵ *Id.* at 28.

⁴⁶ *See, e.g.*, paragraphs 50 to 53 below (describing formularies developed by Humana’s vertically-integrated PBM).

prescription drug plans alter their reimbursement rates and formularies to reduce pharmacy costs.⁴⁷

39. Ordinarily, after a PBM pays a pharmacy for a pharmaceutical product, the PBM will seek payment from the plan sponsor's (e.g., the employer, union benefit plan, etc.) pharmacy plan. Such payments are governed by contracts that are negotiated between the plan sponsors or health insurers and PBMs. These payment arrangements can be rather complex, with several pieces. For example, there is a reimbursement formula, which may include a dispensing fee and an administrative fee. The formula for the plan sponsor reimbursement of the PBM and the formula for PBM reimbursement of the pharmacy often are different and result in numbers that are not equal. Under some contractual arrangements, called "pass through pricing," the plan sponsor pays the PBM the exact same amount that the PBM pays the pharmacy. Under other contractual arrangements, the plan sponsor will be billed more by the PBM than the PBM paid to the pharmacy. Under such an arrangement, the PBM retains the difference in the two prices as part of its compensation.

40. Rebates are another factor in the prices that TPPs pay for pharmaceutical products. Most contracts between plan sponsors and PBMs include a provision requiring the PBM to share some or all of the rebates it receives with plan sponsors.⁴⁸ Rebate sharing helps the PBM to win the business of plan sponsors by lowering the net price of branded pharmaceuticals dispensed in the sponsor's pharmacy programs. This sharing can take a number of forms. In the simplest form of

⁴⁷ KAISER FAMILY FOUNDATION, FOLLOW THE PILL: UNDERSTANDING THE U.S. COMMERCIAL PHARMACEUTICAL SUPPLY CHAIN 14, 19 (2005), <https://www.kff.org/other/report/follow-the-pill-understanding-the-u-s/>.

⁴⁸ 91 percent of large employer plans and 74 percent of small employer plans report receiving rebates in 2017. PBMI, 2017 TRENDS IN DRUG BENEFIT DESIGN 21, fig. 20 (2017).

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rebate sharing, the PBM agrees to give a fixed percentage of the rebates it receives to the plan sponsor.

41. The most common form of rebate sharing is the rebate guarantee.⁴⁹ Rebate guarantees promise the plan sponsor a fixed dollar amount of rebate to be paid for each branded prescription reimbursed. This form of sharing shifts the rebate risk back to the PBM, rather than the plan sponsor. Rebate guarantees can also break the link between the dollar amount of rebates paid by the manufacturer for a particular drug and the amount of rebate dollars received by the prescription drug plan. That is, a plan sponsor will receive the guaranteed amount of rebate on every sale of a branded pharmaceutical, regardless of whether the PBM received any rebates from that pharmaceutical's manufacturer.

42. Still other contractual arrangements employ a hybrid of the two sharing systems above: the PBM will pay the plan sponsor the greater of 100% of rebates or a fixed dollar guarantee per brand prescription. Finally, other contractual arrangements may call for a guaranteed discount; that is, the plan sponsor's total drug spend will not exceed a certain amount.

iv. Fully-Insured Versus Self-Insured TPPs

43. The vast majority of the insured population is insured through private insurer TPPs such as Aetna, Anthem, Cigna, and Kaiser.⁵⁰ Individuals and employer-sponsor TPPs, among others, contract with private insurer TPPs to administer health care benefits, sometimes including

⁴⁹ PBMI, 2014-2015 PRESCRIPTION DRUG BENEFIT COST AND PLAN DESIGN REPORT fig. 34, https://www.pbmi.com/PBMI/Downloads/Sponsored_Reports/2014-2015_Benefit_Design_Report.aspx?WebsiteKey=0a635f1b-bb59-4687-8a69-2a4c2892992b (last visited Mar. 17, 2019).

⁵⁰ As of 2017, over 60 percent of the U.S. population was covered by private insurance, 25 percent covered by Medicaid, and 10 percent are uninsured. Kaiser Family Foundation, Health Insurance Coverage of the Total Population, accessed March 18, 2019 at <https://www.kff.org/other/state-indicator/total-population/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D>

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prescription drug benefits, for their employees. These insurance contracts may take one of two general forms.

- The employer plan sponsor TPP may enter into a “fully-insured” contract with a private insurer TPP, whereby the sponsor pays the private insurer all or part of the health insurance premiums for its employees. In return for these fixed premiums, the insurer accepts most or all of the financial risks of reimbursing the employees’ medical and pharmaceutical expenses during the contract period.
- Alternatively, under a self-funded plan (also referred to as a “self-insured plan”), the employer plan sponsor TPP bears the risk and pays the costs of medical and pharmaceutical expenses rather than paying premiums to a private insurer.⁵¹ In self-insured plans, the insurer is compensated for administering medical and pharmaceutical claims through its provider networks but assumes no pricing risk.

Still other plans contain aspects of both self-funded and fully-insured plans. For instance, some self-insured plans will contract for “stop-loss” coverage, in which the private insurer agrees to reimburse medical or pharmaceutical expenses after some predetermined threshold is met.

Insurer TPPs enter into all of these types of contractual arrangements with plan sponsor TPPs.

44. When an employer plan sponsor has a self-insured plan, it is responsible for paying all covered health expenditures as they occur.

45. With a fully-insured plan, the sponsor TPP pays fixed premiums for employee health benefits. If health expenditures differ from what was expected during the contract term, this risk is borne by the insurer, rather than by the sponsor, but generally for the term of the contract only.

Some fully-insured insurance contracts contain “retrospective rating” clauses that allow the

⁵¹ An annual survey conducted by Kaiser Family Foundation asked a sample of 2,046 employers about the health plans that they offer their employees. Within this sample, over 59 percent of employees receiving health coverage through employer-sponsored plans were participants in self-insured employer plans. KAISER FAMILY FOUNDATION, EMPLOYER HEALTH BENEFITS 2010 ANNUAL SURVEY 10, 154 (2010). The more comprehensive Department of Labor survey of group health plans states that in 2009, 30 percent of group health plans were self-insured, 58 percent were fully-insured, and 12 percent of plans had components of each. U.S. DEPARTMENT OF LABOR, EMPLOYEE BENEFITS SECURITY ADMINISTRATION, GROUP HEALTH PLANS REPORT: ABSTRACT OF 2009 FORM 5500 ANNUAL REPORTS REFLECTING STATISTICAL YEAR FILINGS tbl. A2 (2012), <http://www.dol.gov/ebsa/pdf/ACA-ARC2012.pdf>.

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insurer to collect additional funds from the plan sponsor should the plan's medical expenses exceed premium income by a predetermined amount.⁵²

v. Examples of Particular TPPs

46. **Local 282.** There is only one Named Plaintiff that purports to be a TPP: Local 282 Welfare Trust Fund ("Local 282"). Local 282 operates under a collective bargaining agreement between an employer group and a labor union.⁵³ As the moniker "Welfare Trust Fund" implies, such funds are operated for the benefit of union members, without the need to earn profits for stockholders as is the case with public insurers.⁵⁴ Local 282 is an example of one type of multiemployer plan known as a Taft-Hartley plan.⁵⁵ Taft-Hartley plans are characterized by a joint board of trustees consisting of equal representation for employers and employees. This board is ultimately responsible for the administration of the plan. While the Trustees often consult with professional health insurance brokers, and may contract with firms like PBMs to administer certain aspects of the plan, the actual operation of the plan is handled by individuals who are not health care professionals.⁵⁶ There are also multiemployer plans that are not Taft-Hartley plans. These plans also are established through collective bargaining agreements but are not administered by a board of trustees.⁵⁷

⁵² See Bluhm, *supra* n.40.

⁵³ See Local 282 Agreement and Decl. of Trust 1 ("Agreement and Declaration of Trust"); *see also* Local 282 Dep. 171:20-172:1.

⁵⁴ Local 282 is a non-profit organization. *See* Bulding Dep. at 58:11-21 ("The Local 282 Welfare Trust Fund is a self-insured fund, it's a non-for-profit.").

⁵⁵ See Class Pls.' Opp. to the Decl. of S. Kadosh 5, ECF No. 791 ("[T]he class is comprised of individual consumers and a single regional Taft-Hartley welfare trust fund.").

⁵⁶ See Bulding Dep. 181:16-185:14; *see also* Agreement and Declaration of Trust Art. II, Sec. 3; *Board of Trustees*, TEAMSTERS UNION LOCAL 282, <http://www.teamsterslocal282.com/benefits/board-of-trustees.html> (last visited Mar. 14, 2019).

⁵⁷ See *What is a Multiemployer Plan?*, INTERNATIONAL FOUNDATION OF EMPLOYEE BENEFIT PLANS,

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47. According to the Department of Labor, multiemployer benefit plans such as Local 282 represent less than 4 percent of all group health plans.⁵⁸ In addition to being numerically small, such plans are organized, funded, and operated totally differently than other group health plans. In addition to being administered by a board of trustees rather than corporate governance like private insurers, they are funded primarily, if not exclusively, by employer-sponsor contributions determined by the collective bargaining agreement. These employer contributions may be supplemented by employee contributions and investment income. Any financial shortfall must be made up by additional funds from the employer-sponsors or investment income. The employer-sponsors may be obligated by their collective bargaining agreement to make up the shortfall when it occurs, or by increasing contributions in the next collective bargaining agreement.⁵⁹

48. Accordingly, Local 282 bears no ultimate financial responsibility for the drugs dispensed to its insured members; rather, its costs are paid in full by the employers that pay into it. In addition, unlike some other TPPs, which may even own or control their own PBMs (see paragraphs 50 to 61 below), Local 282 has little or no involvement in negotiating with drug manufacturers or even with PBMs. Instead, it relies on an outside consultant, The Segal Group, to serve “as the sole means through which Local 282 communicates, negotiates, and contracts with PBMs.”⁶⁰ As its fact sheet from this case states, “Local 282 does not receive and is not in

<http://www.ifebp.org/news/featuredtopics/multiemployer/Pages/default.aspx> (last visited Mar. 18, 2019).

⁵⁸ Of the 50,216 group health plans of all types in the US in 2009, only 1,801, or less than 4 percent, are multiemployer, collectively bargained plans like Local 282. U.S. DEPARTMENT OF LABOR, EMPLOYEE BENEFITS SECURITY ADMINISTRATION, GROUP HEALTH PLANS REPORT: ABSTRACT OF 2009 FORM 5500 ANNUAL REPORTS REFLECTING STATISTICAL YEAR FILINGS 6, tbl. A2 (2012), <http://www.dol.gov/ebsa/pdf/ACA-ARC2012.pdf>.

⁵⁹ Bulding Dep. at 59:23-25.

⁶⁰ Mem. and Order 5, ECF No. 1474.

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possession of rebate information for individual epinephrine auto-injector products.”⁶¹ The deposition of Local 282 also indicated that Local 282 had little familiarity with how negotiations concerning pharmaceutical rebates take place.⁶²

49. Other TPPs in the putative class for which Local 282 would serve as a representative include some of the most sophisticated and largest companies in the U.S. I discuss four examples of such TPPs in the following paragraphs.

50. **Humana.** Humana is a public, for-profit health insurance company that covers around 13 million lives. [REDACTED]

[REDACTED]⁶³ It ranks 57th on the Fortune 500 list of the nation’s largest corporations. Humana’s business model encompasses most types of health insurance. It offers fully-insured plans and various types of managed care plans. It also administers self-insured plans and managed care plans for the Department of Defense through Humana Military Healthcare Services. Humana also operates Medicare Advantage plans, Medicare Part D prescription plans, and Medicare Supplement (“Medigap”) plans. Humana creates its own formularies that consist of four or five tiers, with each tier representing a different cost share (e.g., co-payment or co-insurance).⁶⁴

⁶¹ Local 282 Pl. Fact Sheet, Resp. to Question 4(j).

⁶² See Bulding Dep. at 312:17-313:1 (Q: “[N]egotiated payment amounts, discounts, and rebate or discount amounts for epinephrine Auto-Injector products,’ that’s the part that you’re not prepared to testify to today?” A: “I was not part of the negotiations so I can’t answer those questions.”); *id.* at 238:9-239:1 (Q: “When negotiating prescription drug coverage, what are the factors that Local 282 or the consultants that it hires considers?” A: “I don’t know.” Q: “On what basis does Local 282 make any decision as to whether to cover or not cover epinephrine Auto-Injector products under its health plans?” A: “Absolutely nothing.”); *id.* at 253:10-254:7 (Q: “So you don’t review the actual document that the PBM submits?” A: “Correct.”); *id.* at 290:18-291:6 (Q: “So the client would receive one hundred percent of the rebates that [a PBM] received?” A: “I don’t know.”); *id.* at 295:11-23.

⁶³ Humana Dep. at 18:1–13.

⁶⁴ *Id.* at 22:2–23:11.

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51. [REDACTED]

[REDACTED]

[REDACTED]⁶⁶ It does so by sending out a “bid grid” to the manufacturers soliciting manufacturer rebate offers for various formulary positions.⁶⁷

52. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]⁶⁹ If a branded drug is subject to prior authorization, Humana’s plans will not cover it unless the patient’s doctor explicitly authorizes the branded drug by name.⁷⁰ Likewise, if a branded drug is subject to step therapy, the patient must first try an alternative product before Humana will cover it.⁷¹

53. [REDACTED]

[REDACTED]

[REDACTED]⁷³ [REDACTED]o

⁶⁵ *Id.* at 19:13–25.

⁶⁶ *Id.* at 213:15–214:10.

⁶⁷ *Id.* at 214:11–14, 216:22–217:7.

⁶⁸ *Id.* at 35:17–22.

⁶⁹ *Id.* at 35:23–36:3.

⁷⁰ *Id.* at 58:8–19.

⁷¹ *Id.* at 59:5–16.

⁷² *Id.* at 219:13–16.

⁷³ *Id.* at 223:18–24.

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[REDACTED]

[REDACTED]⁷⁴

54. **Kaiser Permanente.** Kaiser Permanente is another health insurer.⁷⁵ It has more than 12 million dues-paying members, spread over eight geographic regions.⁷⁶ Kaiser has thousands of plans.⁷⁷ Some plans have co-payments or co-insurance.⁷⁸ Some are high-deductible plans with health savings accounts.⁷⁹ Kaiser maintains one six-tier formulary for Medicare nationwide, and a different commercial formulary for each of its eight geographic regions.⁸⁰ The commercial formulary may or may not use tiers, depending on a particular patient's individual benefit design and the region he or she lives in.⁸¹

55. Kaiser enlists outside PBMs only for the limited purpose of adjudicating claims.⁸² Rather than use the other services that PBMs offer (such as negotiating rebates), Kaiser contracts with pharmaceutical manufacturers on its own.⁸³ Unlike Humana, however, Kaiser does not use a vertically integrated PBM.⁸⁴ Rather than negotiating for rebates, Kaiser “negotiate[s] for

⁷⁴ *Id.* at 223:25–224:19.

⁷⁵ *Shia Dep.* at 27:4–15.

⁷⁶ *Id.* at 27:16–28:22.

⁷⁷ *Id.* at 32:23–24.

⁷⁸ *Id.* at 32:4–33:8.

⁷⁹ *Id.* at 160:21–25.

⁸⁰ *Id.* at 27:16–24, 33:13–34:11, 49:14–21; 93:6–11 (the California formularies do not have tiers).

⁸¹ *Id.* at 47:13–48:1; 93:6–11.

⁸² *Id.* at 29:17–24.

⁸³ *Id.* at 30:15–18.

⁸⁴ *Id.* at 182:22 (“We are not a PBM.”).

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discounts up front,”⁸⁵ which it believes allows it to realize savings earlier and to avoid the administrative work associated with collecting retrospective rebates.⁸⁶

56. **Cigna.** Cigna is yet another TPP that would be included in the class for which Local 282 would serve as the sole TPP representative.⁸⁷ Cigna offers an integrated package of both medical and pharmacy benefits.⁸⁸ Since 2007, Cigna has managed about 91 different formularies.⁸⁹ Those formularies, in turn, have varying benefit structures, ranging from two tiers to five tiers.⁹⁰

57. Cigna’s clients include both fully-insured and self-insured employers.⁹¹ Cigna’s fully-insured clients pay Cigna a premium every month for their membership, and in return, Cigna “takes care of the claims experience and expenses associated with that relationship.”⁹²

Meanwhile, Cigna’s self-insured clients have an ERISA plan and are themselves responsible for their health benefit coverage.⁹³ Those clients purchase administrative services and stop-loss protection from Cigna, whereby Cigna will cover any expenses incurred above a predetermined annual dollar amount.⁹⁴

58. About eighty percent of Cigna’s clients are self-insured.⁹⁵ The smallest employs about fifty people; the largest employs about 20,000.⁹⁶ The self-insured employers determine their

⁸⁵ *Id.* at 183:25–184:1.

⁸⁶ *Id.* at 82:20–83:2.

⁸⁷ Kronberg Dep. at 26:20–22 (“Cigna is a healthcare company.”).

⁸⁸ *Id.* at 26:24–28:4.

⁸⁹ *Id.* at 181:3–183:18.

⁹⁰ *Id.* at 54:3–55:18.

⁹¹ *Id.* at 30:4–8.

⁹² *Id.* at 30:10–21.

⁹³ *Id.* at 30:22–31:1.

⁹⁴ *Id.* at 31:5–19.

⁹⁵ *Id.* at 32:6–9.

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employees' co-insurance or co-pay, which vary all the way from zero to the full cost of a drug.⁹⁷

Pharmacy benefits vary no less for patients covered under an employer's fully-insured plan:

There are literally millions of different permutations from which employers may choose.⁹⁸

59. About seventy percent of Cigna's customers—including all of its fully-insured clients—receive both medical and pharmacy benefits from Cigna; the 30 percent that do not generally look to a true PBM for pharmaceutical benefits.⁹⁹

60. For the majority of its customers (reaching about 7.5 million lives), Cigna effectively serves as a PBM.¹⁰⁰ Like a PBM, Cigna negotiates with pharmaceutical manufacturers for rebates, although it does not seek administrative fees.¹⁰¹ Also like a PBM, Cigna ordinarily receives higher rebates with respect to formularies that include step edits or under prior authorization controls.¹⁰²

61. Cigna does not always share rebates with its clients. Some self-insured clients negotiate for the rebate value to be passed through directly.¹⁰³ But other self-insured clients allow Cigna to retain the rebates in exchange for an up-front reduction in fees.¹⁰⁴ Rebates generally are passed through to fully-insured clients in the form of lower premiums.¹⁰⁵

⁹⁶ *Id.* at 32:17–22.

⁹⁷ *Id.* at 32:23–34:13.

⁹⁸ *Id.* at 36:18–37:11.

⁹⁹ *Id.* at 28:5–22; 31:20–22.

¹⁰⁰ *Id.* at 28:23–29:14; 45:5–21.

¹⁰¹ *Id.* at 22:13–15, 63:15–17.

¹⁰² *Id.* at 69:7–16.

¹⁰³ *Id.* at 63:6–11.

¹⁰⁴ *Id.* at 63:12–14.

¹⁰⁵ *Id.* at 63:2–3.

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62. **Anthem.** Anthem is another TPP and member of the would-be class in this case.¹⁰⁶ Like Cigna, Anthem offers both medical and pharmacy benefits.¹⁰⁷ [REDACTED]

[REDACTED]¹⁰⁸ As a result, Anthem's clients indirectly use Express Scripts as their PBM.¹⁰⁹ That is not to say, however, that Anthem does not have a seat at the bargaining table. For some clients, including Anthem, Express Scripts makes available a select client option contract, or SCO, by which a pharmaceutical manufacturer can offer a drug at a specific position to a single targeted Express Scripts client only.¹¹⁰ [REDACTED]

[REDACTED]¹¹¹

V. ASCERTAINABILITY

63. Determining who is included and excluded from a proposed class is a fundamental issue in class action litigation. I have examined in detail much of the data provided in discovery in this matter, covering millions of lives and transactions. Based on that analysis, I do not believe that the basic task of identifying who is included or excluded from the class may be done with these data.¹¹² In addition, Plaintiffs have not provided a reliable methodology for identifying

¹⁰⁶ Minton Dep. at 28:17–21.

¹⁰⁷ *Id.* at 29:2–14.

¹⁰⁸ *Id.* at 16:9–15.

¹⁰⁹ *Id.* at 29:15–30:2.

¹¹⁰ *Id.* at 17:23–18:6.

¹¹¹ *Id.* at 21:9–22:6.

¹¹² Data I have examined include: Aetna00019823.xlsx (Aetna data); ANTH-EPI 03619.XLSB, ANTH-EPI 03620.XLSB, ANTH-EPI 03621.XLSB, and ANTH-EPI 03622.XLSB (Anthem data); BCEPI000216.xlsx and BCEPI000217.xlsx (Blue Cross Blue Shield of Arizona data); ARBCBS00000001.txt (Blue Cross Blue Shield of Arkansas data); BCEPI000216.xlsx and BCEPI000217.xlsx (Blue Cross Blue Shield of Arizona data); ARBCBS00000001.txt (Blue Cross Blue Shield of Arkansas data); BCBS-MA00003073.xlsb (Blue Cross Blue Shield of Massachusetts data); BS-CA0003518_001.xls (Blue Shield of California data); CAREFIRST_MDL02785_001650.xls (CareFirst data); CVSCM_EPIDATA_00001.txt (CVS data);

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who is included or excluded from the class. In this section, I will explain the bases for these conclusions.

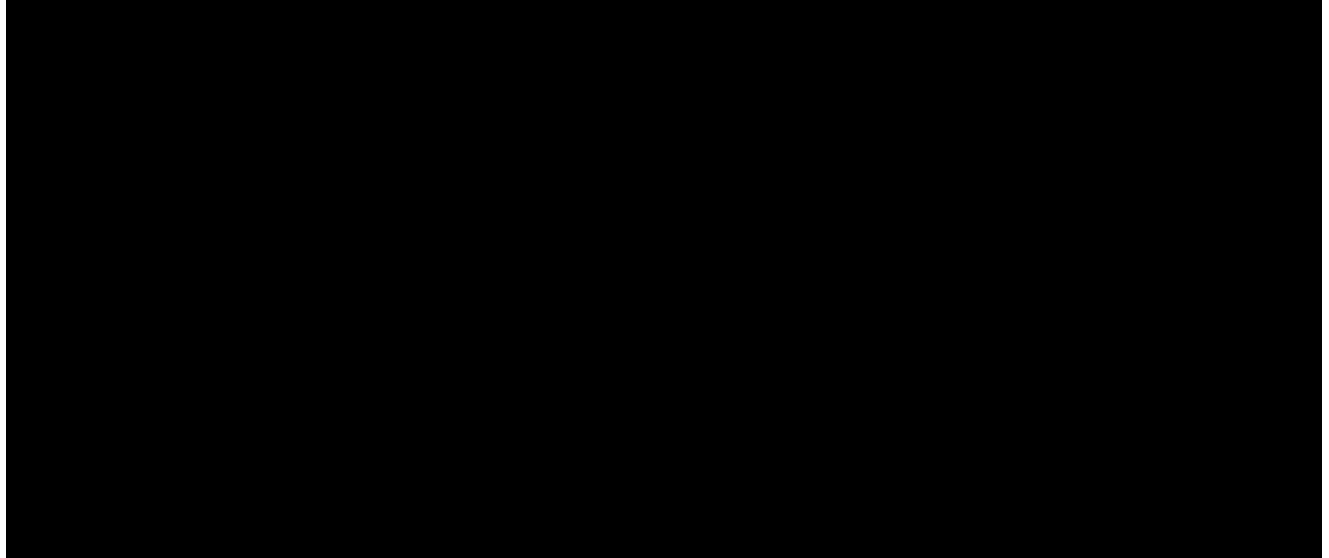
64. As a threshold matter, potential class members must be identifiable. At the outset, I note that, based on my review, I am not aware of any data produced in discovery that include names, addresses or other contact information of the potential class members. I understand that data were produced in this litigation from certain non-party TPPs and PBMs. Those data contain information on particular EpiPen transactions, including amounts paid by the claimant for the EpiPen purchases. However, while those data often contain a numerical code for a patient, the data contain no patient names and no patient addresses or other means of identifying individual class members. For example, Table 1 below provides examples of member or claim ID information fields, if any, contained in the numerous data files I examined.

ES_0000017.txt and ES_0000018.txt (Express Scripts data); Horizon00013639.xlsx (Horizon data); HUM000002.xlsx (Humana data); EAI 00243753.xlsx to EAI 00243755.xlsx, EAI 00243984.xlsx to EAI 00243988.xlsx, EAI0243989.xlsx to EAI0244013.xlsx (Optum data); HPHC000001 - CONFIDENTIAL - Copy of Copy of HPH_EpiPens_2007_2011_PHI_Redacted.XLSX, HPHC000002.XLSX, and HPHC000003.XLSX (Harvard Pilgrim Health Care); and Coupons 01.16 – 08.16 (HIGHLY CONFIDENTIAL).xlsx, Coupons 07.15 - 12.15 (HIGHLY CONFIDENTIAL).xlsx and Coupons 02.13-06.15 (HIGHLY CONFIDENTIAL).xlsx (Mylan coupon data).

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Table 1

Claims Data Provided in Discovery Does Not Include Claimant Identities



65. I understand that the record does not contain patient names or other information that could be used to identify particular class members. None of the data that I have examined from the numerous insurers and PBMs produced in this matter would, standing alone, allow the parties or the Court to ascertain the identities of individual class members.

66. I understand that many of the non-parties who produced data “de-identified” the data in order to avoid the production of protected health information, and therefore patient ID numbers and other identifiers may not even correspond to actual patient records. Other datasets may include a patient ID number or claim number that could potentially be connected to the identity of the patient; however, these data have not been produced in this matter. Doing so would require extensive amounts of information from TPPs (and potentially pharmacies). Extensive further discovery would be required to determine if such connections are possible.

67. If the data were to become available to link these numerous files with potential class member identities, the next threshold issue for class membership would then have to be

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addressed – identifying which individuals or entities actually paid for EpiPen devices. The proposed classes, as defined by the Plaintiffs, only include individuals or entities that in fact “paid or provided reimbursement for some or all of the purchase price of Branded or AB-rated generic EpiPens.”¹¹³

68. Based on my review of Plaintiffs’ Motion for Class Certification and other filings submitted in support of that Motion, the Plaintiffs have not proposed any methodology for determining who actually paid for EpiPen products (and thus would be eligible for inclusion in a class) and who received EpiPen products but did not pay for them (and thus would fall outside Plaintiffs’ class definitions). Nor have Plaintiffs identified any data that would be sufficient to make these determinations. As discussed below, based on the available data, it is impossible to ascertain which consumers fit within Plaintiffs’ class definitions – whether those consumers are cash payors or insured consumers.

A. Cash Payors

69. According to the Kaiser Family Foundation, the percentage of uninsured consumers in the U.S. population was as high as 17% during the class period.¹¹⁴ As noted above, the discovery produced in this case does include data from insurers and PBMs. Insurers and PBMs, however, do not have relationships with cash customers, and therefore would not have information on their purchases. Thus, the available claims data, which were from insurers and PBMs, do not include information on cash customers.¹¹⁵

¹¹³ See paragraph 10 above.

¹¹⁴ *Key Facts About the Uninsured Population*, KAISER FAMILY FOUNDATION fig.1, (Dec. 7, 2018), <https://www.kff.org/uninsured/fact-sheet/key-facts-about-the-uninsured-population/>.

¹¹⁵ Mylan’s coupon program was available only to insured customers. *See Access and Savings Programs*, MYLAN SPECIALTY, <https://www.epipen.com/paying-for-epipen-and-generic/> (last visited Mar. 16, 2019).

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70. As illustrated in Figure 1 above, which depicts the flow of pharmaceutical product sales, retail pharmacies sell EpiPen products to cash customers. Therefore, any record of such cash sales would be in the possession of these retail pharmacies. However, my understanding is that Plaintiffs did not obtain pharmacy data as part of discovery in this matter.

71. In addition, if Plaintiffs were to attempt to obtain and analyze pharmacy data to identify class members, that process would be difficult, if not impossible. As of 2015, there were 65,280 retail pharmacies serving both cash and insured customers in the United States.¹¹⁶ And while 41,684 of these pharmacies consist of chain drug, mass market and grocery stores such as Walgreens, CVS, Walmart, Publix, RiteAid, Costco, and Kroger, among others, many are not. In fact, in 2015, there were 23,596 independent pharmacies in the United States.¹¹⁷ These independent pharmacies are major players in the industry, as about one-third of all prescriptions are filled at independent pharmacies.¹¹⁸ To identify all consumers who paid cash for EpiPen products, Plaintiffs would need to obtain data from each of these thousands of pharmacies. Plaintiffs, to my knowledge, have not attempted to undertake this process.

72. Another factor that would make it difficult to ascertain cash payors using pharmacy data relates to consolidations in the retail pharmacy industry.¹¹⁹ Data, if it exists, would have to be

¹¹⁶ Dima Mazen Qato et al., *The Availability of Pharmacies in the United States: 2007–2015*, 12(8) PLOS ONE 1, 5 tbl. 1 (2017), <https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0183172>.

¹¹⁷ *Id.*

¹¹⁸ *Independent Pharmacy Today*, NATIONAL COMMUNITY PHARMACISTS ASSOCIATION, <https://www.ncpanet.org/home/independent-pharmacy-today> (last visited March 17, 2019).

¹¹⁹ Examples of consolidations in the retail pharmacy space include Walgreen's purchases of Duane Reade, Rite Aid and Fred's pharmacies; CVS's acquisition of Target, Eckerd and Albertson pharmacies; and Rite Aid's acquisition of Eckerd stores. See Timothy Aungst, *Pharmacy Wars: An Era of Acquisition, Mergers, and Losses*, PHARMACY TIMES (Mar. 6, 2018), <https://www.pharmacytimes.com/contributor/timothy-aungst-pharmd/2018/03/pharmacy-wars-an-era-of-acquisition-mergers-and-losses>; see also Daphne Howland, *Walgreens to Take Over 185 Fred's Pharmacies*, RETAIL DIVE (Sept. 11, 2018), <https://www.retaildive.com/news/walgreens-to-take-over-185-freds-pharmacies/532045/>.

obtained from numerous companies that have been acquired and may not have preserved or retained such data in a reasonably accessible form.

73. For that reason, ascertaining the identity of all cash payers would be difficult, if not impossible, and Plaintiffs have identified no methodology for doing so.

B. Insured Consumers

74. Plaintiffs also have not proposed a methodology for identifying which insured consumers who filled prescriptions for EpiPen products are included in the class. As noted above, under Plaintiffs' class definitions, insured consumers only fit within the class definitions if, among other requirements, they (1) paid a positive price for an EpiPen product, and (2) did not have the same copayment for branded and generic pharmaceutical products. As discussed below, Plaintiffs have not proposed a methodology for excluding insured class members who do not meet these requirements.

i. No Process for Excluding Insured Consumers Who Paid Nothing

75. Whether an insured consumer had a transaction involving an EpiPen may be seen in the PBM and insurer data provided in discovery in this matter. Specifically, the data include fields identifying the product in each claim. The specific field names vary slightly, but include a field identifying the NDC, or National Drug Code, which is a standard identifier code for pharmaceutical products.¹²⁰ For example, Aetna has a field labeled "NDC_CD" in column AQ, while Anthem and BCBS AZ each have a field labelled "NDC."¹²¹ Some files also include a

¹²⁰ According to the FDA, "Drug products are identified and reported using a unique, three-segment number, called the National Drug Code (NDC), which serves as a universal product identifier for drugs." *Drug Approvals and Databases: National Drug Code Directory*, U.S. FOOD & DRUG ADMIN, <https://www.fda.gov/drugs/informationondrugs/ucm142438.htm> (last visited Mar. 16, 2019).

¹²¹ ANTH-EPI 03619.XLSB, ANTH-EPI 03620.XLSB, ANTH-EPI 03621.XLSB, and ANTH-EPI 03622.XLSB (Anthem data); BCEPI000216.xlsx and BCEPI000217.xlsx (Blue Cross Blue Shield of Arizona data)

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product description or a product label field. However, the NDC codes may be verified with the FDA website to identify Mylan's EpiPen products.¹²²

76. Whether the customer associated with the transaction actually paid a positive price for the EpiPen products requires examining whether other factors resulted in zero out-of-pocket costs for the customer.

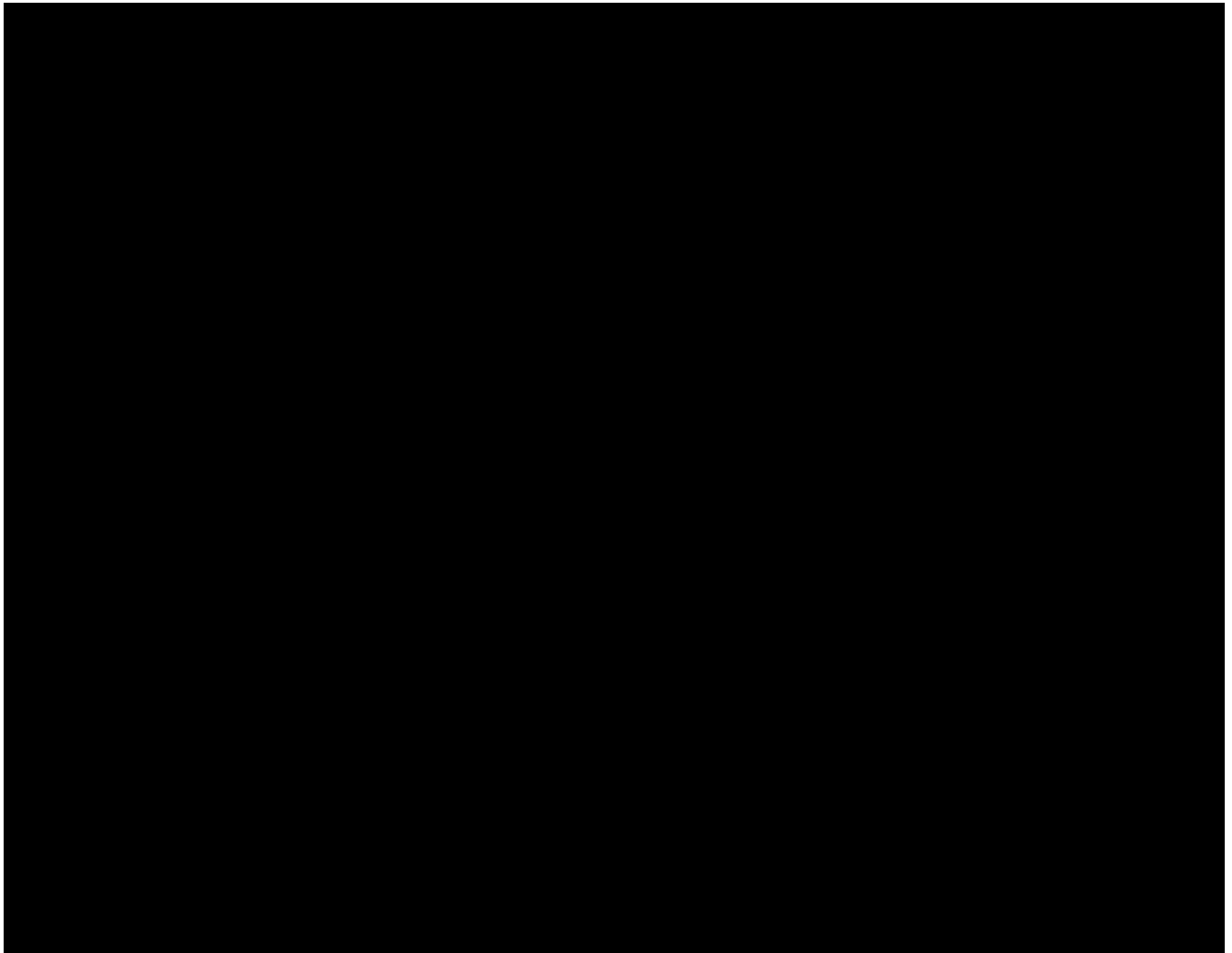
77. The PBM and insurer data files I examined each include a field that provides some information that relates to what the member paid, along with other related information, such as copay and coinsurance. These fields are not standard across the data files, nor are these other fields included in each data file. Table 2 provides examples of the field names and values for various of these terms.

¹²² The FDA maintains a searchable NDC directory. *See National Drug Code Directory*, U.S. FOOD & DRUG ADMIN., <https://www.accessdata.fda.gov/scripts/cder/ndc/index.cfm> (last visit Mar. 18, 2019). NDC codes in the data files may not include the hyphens that are seen in the NDC directory, but may be easily matched nonetheless. The NDC code has five digits followed by a hyphen, then three digits followed by a hyphen before the last two digits. That is NDC does 49502-500-02, which is a version of EpiPen Auto-Injector, may be represented in the data without hyphens as 4950250002.

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Table 2

Examples of Fields Containing Payment Terms



78. Critically, the fact that the records in these particular datasets show a positive amount paid for an EpiPen device, does not necessarily mean that the customer incurred out-of-pocket costs for the product. As discussed below, this discrepancy may be due circumstances such as the use of Mylan coupons or health savings accounts that were not funded by the member.

79. **Mylan Coupons.** Mylan instituted a program by which it provided coupons to individuals with insurance to offset out-of-pocket expenses for the purchase of both its branded

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EpiPen and its authorized generic.¹²³ Mylan produced data in this matter associated with its coupon program.¹²⁴ A tabulation of these data shows that over the period February 2013 through August 2016, [REDACTED]

[REDACTED].¹²⁵

80. I understand that Mylan does not have data on the identities or contact information for those using the coupons.¹²⁶ If these data could be obtained, it still would be difficult, if not impossible, to link the purchases in the Mylan data to insurer or PBM data to identify which consumers, who may have a positive payment in the insurer or PBM data, had their payments reduced to zero through the coupon program. This makes sense given that the PBM or insurer does not process the coupon. I understand that the retail pharmacies process the coupon transactions. As pharmacy data were not provided in discovery, I cannot tell if Mylan coupon data are retained by the pharmacy and if those data may be linked to insurer or PBM data. Nor

¹²³ Mylan's website describes the programs: "The My EpiPen Savings Card® can provide you up to \$300 in savings* for each EpiPen 2-Pak® carton per prescription refill. The My EpiPen Savings Card® helps eligible patients who have commercial health insurance save on out-of-pocket costs. The My EpiPen Savings Card® is reusable for up to six EpiPen 2-Pak® cartons so you can have EpiPen® Auto-Injectors available in different locations. Mylan's MyGenericEAI Savings Card can provide you up to \$25 in savings* for each two-pack of Mylan's Epinephrine Injection, USP Auto-Injector (its authorized generic for EpiPen®) per prescription refill. The MyGenericEAI Savings Card helps eligible patients who have commercial health insurance save on out-of-pocket costs. Mylan's MyGenericEAI Savings Card is reusable for up to three (3) two-packs of Mylan's Epinephrine Injection, USP Auto-Injector so you can have epinephrine auto-injectors available in different locations." *See Access and Savings Programs*, MYLAN SPECIALTY, <https://www.epipen.com/paying-for-epipen-and-generic/> (last visited Mar. 16, 2019).

¹²⁴ Coupons 01.16 – 08.16 (HIGHLY CONFIDENTIAL).xlsx, Coupons 07.15 -12.15 (HIGHLY CONFIDENTIAL).xlsx and Coupons 02.13-06.15 (HIGHLY CONFIDENTIAL).xlsx (Mylan coupon data).

¹²⁵ [REDACTED]

¹²⁶ [REDACTED]

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have Plaintiffs proposed a methodology or data for ascertaining these individuals in order to exclude them from the putative class.

81. **Health Savings Accounts.** Another reason that a consumer may not incur out-of-pocket costs in obtaining EpiPen products is that they may use a health savings account that is completely funded by an employer. First of all, the insurer and PBM data I examined in this case do not include any field indicating whether an HSA was used to pay for a copay or coinsurance obligation. Second, even they did, the funding source(s) for each claimant's HSA would require individualized inquiry, likely involving asking administrators for each plan to identify benefit terms, or possibly claimant interviews. For example, Plaintiff Amell revealed in deposition that she used an HSA fully funded by her husband's employer to make all of her EpiPen product purchases since at least 2013.¹²⁷ Plaintiff Amell has not provided any evidence that she paid anything for her EpiPen products. Had she not been a named plaintiff, based on my analysis, there would be no way to determine if she were part of the class. Plaintiffs have not identified any source of data that could be used to identify individuals who paid nothing for their EpiPen products as a result of an employer fully-funded health savings account, or any methodology for using such data to ascertain these individuals to exclude them from the class.

ii. No Process for Identifying Consumers with “flat” copays

82. As noted above, Plaintiffs specifically exclude from the class individuals who have “flat” copays.¹²⁸ That is, Plaintiffs exclude individuals who would have paid the same copay for the branded EpiPen as a generic version. None of the data I examined from the numerous insurers

¹²⁷ Amell Dep. at 105:7-106:7, 148:23-149:14.

¹²⁸ Plaintiffs' MOL at 28-29.

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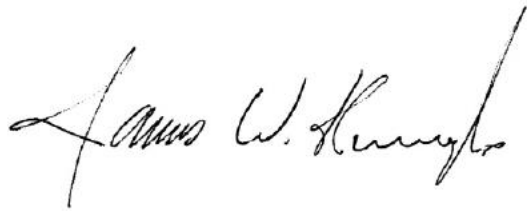
and PBMs provides information on whether a generic copay for epinephrine auto-injectors would be the same as for a branded EpiPen for the same member, plan and date.

83. As noted previously, the various data files contain information on the specific product for which a claim is submitted, by including the NDC code. Thus, claims for branded vs. generic products could be determined. However, the various insurer and PBM data files do not always include copay information on the claims paid, and do not indicate if the benefit plan had a flat copay feature. Plaintiffs have identified no data or methodology for ascertaining individuals who paid flat copays. In my experience, the data I have encountered will generally include the consumer's copayment contribution. However, these data generally do not include information on the copayment the consumer *would* have made if purchasing a generic. Therefore, without information on both brand and generic copayments, it would not be possible to identify flat copay consumers and exclude them from the class. Based on my experience, individualized inquiry into the contract terms of the individual class members' health insurance plans would be required to identify these individuals and exclude them from the class.

84. In sum, the insurer and PBM data I have reviewed that have been produced in discovery in this matter are insufficient to identify all the relevant class members, with cash customers being a substantial missing group, and cannot be used to exclude individuals from the class who did not actually pay for an EpiPen device. The data do not contain any information for each claimant on the generic copay that is part of their benefit plan, and therefore Plaintiffs cannot exclude such individuals from the class on this basis, as they propose. Thus, based on the data and other materials I have reviewed, the Plaintiffs have not identified a methodology or presented data for identifying which individuals should be excluded or included in the class.

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Signed this 18th day of March, 2019.

A handwritten signature in black ink, appearing to read "James W. Henneke". The signature is written in a cursive style with a large, sweeping initial "J".

APPENDIX A

NAME

James W. Hughes

ADDRESS

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DEGREES:

Ph.D., Economics, The University of Michigan, 1987
M.A., Economics, Boston University, 1978
A.B., International and Comparative Studies, Boston University,
1977, *summa cum laude*, with distinction

FIELDS:

Industrial Organization and Antitrust Policy; Law and Economics; Health
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Thesis: The Economics of Medical Malpractice Reform

**ACADEMIC
POSITIONS:**

BATES COLLEGE, Lewiston, ME, 2005-.
Thomas Sowell Professor of Economics

BATES COLLEGE, Lewiston, ME, 2004-2005.
Professor of Economics

BATES COLLEGE, Lewiston, ME, 1999-2006.
Chair, Department of Economics

BATES COLLEGE, Lewiston, ME, 1997-2004.
Associate Professor of Economics

BATES COLLEGE, Lewiston, ME, 1992-1997.
Assistant Professor of Economics

AMHERST COLLEGE, Amherst, MA, 1987-1992.
Assistant Professor of Economics

STATE UNIVERSITY OF NEW YORK AT ALBANY, Albany,
NY, 1986-1987.
Assistant Professor of Economics

**ARTICLES IN
REFEREED
JOURNALS:**

“Finding the Lost Jockeys,” (with Debra Barbezat), *Historical Methods*;
A Journal of Quantitative and Interdisciplinary History, v. 47, n. 1, 2014,
pp. 19-30.

“A Comparison and Decomposition of Reform-Era Labor Force Participation Rates of China's Ethnic Minorities and Han Majority,” (with M. Maurer-Fazio and Dandan Zhang), *International Journal of Manpower*, v. 31 n. 2, 2010, pp. 138-162 [also cited as IZA Discussion Paper #4148, April 2009].

“An Ocean Formed from One Hundred Rivers: The Effects of Ethnicity, Gender, Marriage, and Location on Labor Force Participation in Urban China,” (with M. Maurer-Fazio and Dandan Zhang), in Gender, China, and the World Trade Organization, Gunseli Berik, Xiaoyuan Dong, and Gale Summerfield, eds., (London and New York, Routledge, Taylor and Francis Group, 2009) pp. 157-185.

“海纳百川：民族、性别、婚姻、地区等因素对中国城市地区劳动参与的作用和影响” (with M. Maurer-Fazio and Dandan Zhang), (An Ocean Formed from One Hundred Rivers: The Effects of Ethnicity, Gender, Marriage, and Location on Labor Force Participation in Urban China,”), in Gunseli Berik, Xiaoyuan Dong, and Gale Summerfield edited 中国经济转型与女性经济 (China's Economic Transition and Feminist Economics) Beijing: Economic Science Press, 2009, pp.130-157.

“An Ocean Formed From One Hundred Rivers: The Effects of Ethnicity, Gender, Marriage and Location on Labor Force Participation in Urban China, (with M. Maurer-Fazio and D. Zhang), *Feminist Economics*, v. 13, n. 3-4, July/October, 2007, pp. 159-187.

“Salary Structure Effects and the Gender Pay Gap in Academia,” (with D. Barbezat), *Research in Higher Education*, v. 46, n 6, September, 2005.

“The Effect of Market Liberalization on the Relative Earnings of Chinese Women,” (with M. Maurer-Fazio) *Journal of Comparative Economics*, v 30, n 4, pp. 709-731, December, 2002 [also cited as William Davidson Working Paper No. 460].

“An Analysis of the Effects of Marital Status, Educational Attainment, and Occupation on the Size and Composition of Urban China's Gender Wage Differentials,” (with M. Maurer-Fazio) *Pacific Economic Review*, v. 7, n. 1, pp. 137-156, February, 2002.

“The Effect of Job Mobility on Academic Salaries,” (with D. Barbezat), *Contemporary Economic Policy*, v. 19, n. 4, October, 2001, pp 409-423.

“Health Consequences of Smoking and Its Regulation,” (with Michael Moore), *Frontiers in Health Policy* v. 4, 2001 pp.31-76 [also cited as NBER Working Paper #7979, October, 2000]

“Accounting for Censoring in Duration Data: An Application to Estimating the Effect of Tort Reforms on the Length of Time to Resolution of Medical Malpractice Claims” (with E. Savoca), *Journal of Applied Statistics* v. 26, n. 2, February, 1999, pp. 219-228

“allocation of litigation costs--American and English rules,” (with Edward Snyder), *The New Palgrave Dictionary of Economics and the Law*, Peter Newman, editor, (London, The Macmillan Press), July, 1998.

“Wal-Mart and Maine: The Effect on Employment and Wages,” (with B. Ketchum), *Maine Business Indicators*, v. 42 n.2, Summer, 1997.

“The Effect of Legal Reforms on the Longevity of Personal Injury Claims,” (with E. Savoca), *International Review of Law and Economics*, v 17, pp. 261-273, June, 1997.

“Basing Point Pricing and the German Steel Cartel: A Look at the 'New Competitive' Theory,” (with Daniel Barbezat), *The Journal of Economic History*, March, 1996, pp. 215-222.

“Litigation Under the English and American Rules: Theory and Evidence,” (with E. Snyder), *The Journal of Law and Economics*, April, 1995, p.225-250.

“Barriers to the Establishment of New Drug Treatment Facilities,” (with F. Porell and H. Pollakowski), *NIDA Services Research Monograph: Access and Financing in Drug Abuse Services* (Gabrielle Denmead and Beatrice A. Rouse, eds.), no. 2, (1994).

“The English Rule for Allocating Legal Costs: Evidence Confronts Theory,” (with E. Snyder), *Journal of Law, Economics, and Organization*, Fall, 1990, pp. 345-380.

“Sex Discrimination in Labor Markets: The Role of Statistical Evidence--Comment,” (with Debra Barbezat), *The American Economic Review*, March, 1990, pp. 277-286.

The Effect of Medical Malpractice Reform Laws on Claim Disposition,” *International Review of Law and Economics*, June, 1989, pp. 57-78.

“Policy Analysis of Medical Malpractice Reforms: What Can We Learn From Claims Data?” (with E. Snyder), *Journal of Business and Economic Statistics*, October, 1989, pp. 423-431.

“Evaluating Medical Malpractice Reforms,” (with E. Snyder),
Contemporary Policy Issues, April, 1989, pp. 83-98.

**EDITED
VOLUMES AND
CONFERENCE
PROCEEDINGS**

“Economic Reforms, Gender, and Changing Patterns of Labor Force Participation in Urban and Rural China,” (with James W. Hughes and Zhang Dandan) in *Conference Proceedings of the 2005 CES International Conference on Sustainable Growth in China*, Chongqing, China. 2005. Volume I-B, pp. 502-510.

“Risk Aversion and the Allocation of Legal Costs,” (with G. Woglom), in David A. Anderson, ed., *DISPUTE RESOLUTION: Bridging the Settlement Gap*, (Greenwich, CT JAI Press, 1996).

MONOGRAPHS:

Cost Estimates for Expanded Substance Abuse Benefits for Medicaid-Eligible Pregnant Women (with M.J. Larson, G. Ritter, P. McQuide, C. Horgan), Institute for Health Policy, The Heller School, Brandeis University, 1993

Socioeconomic Effects of Reducing Emissions of Chlorofluorocarbons (CFCs) in the OECD, Environment Directorate, Organization for Economic Cooperation and Development, Paris, France (1983).

Information Disclosure, President's Regulatory Council, Washington, DC (1982).

**BOOK
REVIEWS:**

Insuring Medical Malpractice, by Frank Sloan, Randall Bovbjerg, and Penny Githens, and *Medical Malpractice on Trial*, by Paul Weiler, reviewed in *Journal of Policy Analysis and Management*, v. 12, n. 2, Spring, 1993, pp. 396-399.

Medicare's New Hospital Payment System, by Louise Russell, reviewed in *Eastern Economic Journal*.

**WORKING
PAPERS:**

“The Role of Productivity in the Demise of the African-American Jockey in 19th Century Thoroughbred Racing,” with Debra Barbezat [*in progress*].

“Human Trafficking in Southeast Asia: Results from a Pilot Project in Vietnam,” with Ngan Dinh, Conor Hughes and Margaret Maurer-Fazio, IZA Discussion Paper DP 8686, September 2017 [under review at *Journal of Human Trafficking*].

“‘Napsterizing’ Pharmaceuticals: Access, Innovation, and Consumer Welfare,” (with M. Moore and E. Snyder), National Bureau of Economic Research Working Paper #9229, October, 2002, revised 2011.

**COURSES
TAUGHT:**

Six Beverages That Changed the World
Economics of Intellectual Property
Law and Economics
Labor Economics
Economic Statistics
Intermediate Microeconomic Theory
Principles of Microeconomics
The Economics of Women, Men, and Work
Environmental and Natural Resource Economics
Sustaining the Masses: Economic Development and Environmental
Protection in the People's Republic of China
Health Economics
Environmental Issues in Economic Development
Earth Under Siege: Global Warming and Atmospheric Change
Principles of Macroeconomics
Property, Liberty, and Law
Industrial Organization and Antitrust Policy
Business and Government

PRESENTATIONS: “The Role of Productivity in the Demise of the African-American Jockey
in 19th Century Thoroughbred Racing—Preliminary Findings,” Maine
Economics Conference, Colby College, April 29, 2017

“Estimating Human Trafficking in Asia Using Household Survey
Results,” International Atlantic Economic Society Conference, Berlin,
Germany, March 23, 2017.

“The Vietnam Migration and Human Trafficking Household Survey:
Results From A Pilot Project,” Forum for Economists International,
Amsterdam, The Netherlands, May 30-June 1, 2015.

“The Vietnam Migration and Human Trafficking Household Survey:
Results From A Pilot Project,” Economics Department Seminar Series,
The University of Maine, September 9, 2014.

“The Vietnam Migration and Human Trafficking Household Survey:
Results From A Pilot Project,” Maine Economics Conference, Colby
College, April 26, 2014.

“The Vietnam Migration and Human Trafficking Household Survey:
Results From A Pilot Project,” Public Works in Progress Lecture, Harvard
Center for Community Engagement, Bates College, April 30, 2014.

“The Vietnam Migration and Human Trafficking Household Survey:
Results From A Pilot Project,” Phillips Lecture, Bates College, January
13, 2014.

“What Will Be Our Legacy: Hi-Tech and High Debt?” 2013 Reunion Lecture, Bates College, June 8, 2013.

“Finding the Lost Jockeys,” Third International Conference on Sport and Society, Cambridge University, Cambridge, England, July 23-25, 2012.

“A Comparison of Reform-Era Labor Force Participation Rates of China and Han Majority” (with M. Maurer-Fazio and Dandan Zhang), Workshop on “Economy and Society Development in China and the World”, Beijing October 13 and 14, 2011, hosted by: Institute of Ethnology and Anthropology Chinese Academy of Social Sciences.

“A Comparison and Decomposition of Reform-Era Labor Force Participation Rates of China's Ethnic Minorities and Han Majority,” (with M. Maurer-Fazio and Dandan Zhang), American Economics Association Annual Meeting, Denver, CO, January, 2011.

“The Economic Status of China's Ethnic Minorities,” (with M. Maurer-Fazio), Western Economics Association Pacific Rim Conference, Hong Kong SAR, China, January, 2005.

“‘Napsterizing’ Pharmaceuticals: Access, Innovation, and Consumer Welfare,” (with M. Moore and E. Snyder), Applied Microeconomics and Economic and Legal Organization, Graduate School of Business, University of Chicago, October, 2002.

“‘Napsterizing’ Pharmaceuticals: Access, Innovation, and Consumer Welfare,” (with M. Moore and E. Snyder), Annual Meeting of the Pharmaceutical Economics and Policy Council, Washington, DC, January 2002.

“The Gender Wage Gap in Urban China: The Effects of Institutional Change,” (with M. Maurer-Fazio), Allied Social Sciences Association, Boston, MA January, 2000.

“The Effect of Job Mobility on Academic Salaries,” (with D. Barbezat), Western Economics Association Meetings, San Diego, CA July, 1999.

“The Economics of the 'Loser-Pays' Rule,” Edward T. Gignoux Inn of Court, Portland, Maine, February 12, 1997.

Keynote Address, Matriculation Dinner for the Class of 1999, Bates College, September 5, 1995.

Breckenridge Lecture, "Is the English Rule Really Cheaper?" Colby College, April 26, 1995.

"Can the English Rule Cure the Ills of Medical Malpractice?" presented to the Androscoggin County Medical Society, March 16, 1995.

"What Blue Cross Knows Can Hurt You: Ethical Dilemmas in Private Medical Insurance," TGIF Lecture, Muskie Archives, March 3, 1995.

"Female Academics: Mobility and the Returns to Seniority," Annual Meetings of the Southern Economics Association, Orlando, FL November 20, 1994.

Breckenridge Lecture, "Economics of the English Rule," Colby College, April 20, 1994.

"Health Care Reform and Medical Malpractice: Smoke or Fire?" TGIF Lecture, Muskie Archives, March 4, 1994.

"Litigation Under the English and American Rules: Theory and Evidence," Annual Meetings of The American Economics Association, Boston, Massachusetts, January 5, 1994.

"Marketable Permits for Chlorofluorocarbon Regulation," Colby College, October, 1993.

"Litigation Under the English and American Rules: Theory and Evidence," Research Seminar in Law and Economics, Harvard Law School, April 7, 1993.

"Litigation Under the English and American Rules: Theory and Evidence," Annual Meeting of the American Law and Economics Association, Yale University, May 1, 1992.

"NIMBY and the Location of Drug Treatment Facilities," National Institute on Drug Abuse, July, 1991.

American Bar Association, "Litigation, Justice, and the Public Good," San Diego, CA April 25-27, 1991.

"Contingent Fees, Litigation, and the Quantity of Litigation," Annual Meeting of the Law and Society Association, May 31, 1990, Berkeley, CA

“The English Rule for Allocating Legal Costs: Evidence Confronts Theory,” Annual Meeting of the Law and Society Association, Madison, WI, June 1, 1989.

“Controlling for Sample Selection in the Analysis of Closed Claim Data,” Annual Meetings of the Western Economics Association, Vancouver, BC, Canada, July, 1988.

“Medical Malpractice Reforms and the Resolution of Claims,” Annual Meetings of the Eastern Economics Association, Arlington, VA March, 1987.

“Is the Sample of Litigated Claims Random? Preliminary Results of a Trivariate Probit Estimator,” Annual Meetings of the Eastern Economics Association, Baltimore, MD, March, 1986.

**PROFESSIONAL
SERVICE**

Referee for: *Journal of Comparative Economics, Journal of Law and Economics, International Review of Law and Economics, Economic Inquiry, Journal of Risk and Insurance, Journal of Law, Economics, and Organization, Journal of Policy Analysis and Management, Behavioral Science and the Law, Social Sciences Quarterly.*

Reviewer for the National Science Foundation.

**GRANTS AND
AWARDS:**

“The Vietnam Migration and Human Trafficking Household Survey, Pilot Project,” Bates Faculty Development Fund Grant, Bates College, 2012-2013.

The Vietnam Migration and Human Trafficking Household Survey, Pilot Project,” PEAP Grant, The Harvard Center for Community Engagement, Bates College, 2012-2013.

Phillips Faculty Fellowship, Bates College, 2012-2013.

“The ‘Dis-Integration’ of American Horse Racing,” Bates College Faculty Development Fund Grant, 2010-2011.

Kroepsch Award for Excellence in Teaching, 2009-2010, Bates College.

“Inspirational Hall of Fame,” Alford Youth Center, Waterville, Maine, May, 2005.

Paganucci Award for Outstanding Community Service, Alford Youth Center, Waterville, Maine, 2004.

Joint Student-Faculty Research Grant (with D. Barsky, ’03),

Freeman Foundation Asian Studies Grant Program, Bates College, 2002.

Curriculum Development Grant (with M. Maurer-Fazio and S. Yang),
Freeman Foundation Asian Studies Grant Program, Bates College, 2002.

Mellon Summer Research Apprenticeship, Bates College, 2000.

Mellon Summer Research Apprenticeship, Bates College, 1998

The President's Fund for Faculty and Curricular Development, Bates
College, 1997-1998.

Curricular Development Grant, Otis Fund, Bates College, 1997.

Mellon Summer Research Apprenticeship, Bates College, 1996.

Kroepsch Award for Excellence in Teaching, 1994-1995, Bates College.

Amherst College Research Award (1991-1992) to examine the effect of
no-fault medical malpractice insurance on the size of awards, the number
of claims, and the number of medical injuries.

Post-Doctoral Research Fellow in the Economics of Mental Health,
Brandeis University, Florence Heller School for Advanced Studies in
Social Welfare, 1990-1991.

Research grant from The Robert Wood Johnson Foundation Medical
Malpractice Program (1987-1988) to examine the long-term effects of
medical malpractice reform legislation on the size, frequency, and
disposition of medical malpractice claims.

Miner D. Crary Fellow, Amherst College, 1988-1989.

**NON-ACADEMIC
POSITIONS:**

LITIGATION CONSULTANT, 1990-
Economic expert for antitrust, regulation, and discrimination litigation.
Retained on several cases involving the pharmaceutical industry, the
prescription benefit manager industry, the environmental control industry,
the synthetic rubber industry, nutritional supplement industry, the hospital
industry, the automobile insurance industry, the sardine market, retail
automobile sales, the retail gasoline market, school photography, musical
instruments, airline transportation, and sex discrimination.

BRANDEIS INSTITUTE FOR HEALTH POLICY, Waltham, MA
1992-1993

Co-Author of a report on the residential housing market in the San
Francisco-Oakland Bay Area, and the effect on property values resulting

from locating residential drug treatment facilities in that market. Co-Author of a study of the effects on Medicaid expenditures of extending coverage for outpatient and residential drug treatment to pregnant drug users.

THE RAND CORPORATION, Santa Monica, CA 1985-1986.
Consultant on a study of the European chlorofluorocarbon industry for the U.S. Environmental Protection Agency. Examined the effect of proposed regulations on competition within the European chemical industry.

ORGANIZATION FOR ECONOMIC COOPERATION AND
DEVELOPMENT, Paris, France, 1982-1983
Author of a report to the Environment Directorate on the socioeconomic implications of chlorofluorocarbon emissions and their control in the OECD nations. Report assessed progress in controlling emissions and quantifies the potential economic effects of further emissions reductions.

SRI INTERNATIONAL, Menlo Park, CA 1981.
Consultant to the Regulatory Analysis and Management Program.
Project included construction of a programming model to assist petroleum refineries in finding the least cost method of reducing emissions of volatile organic chemicals. Author of a manual on the use of information disclosure in regulatory reform for the President's Regulatory Council.

U.S. ENVIRONMENTAL PROTECTION AGENCY,
Washington, DC, 1978-1980.
Economist in the Office of Pesticides and Toxic Substances.
Authored several reports on the effects of regulating toxic chemicals through the use of marketable rights. Responsible for economic analyses of proposed regulations to limit uses of chlorofluorocarbons and asbestos.

APPENDIX B

James W. Hughes

Experience as Testifying Expert Since 2014

In re: Loestrin 24 Antitrust Litigation U.S. District Court RI, MDL No. 2472

In re: Niaspan Antitrust Litigation, U.S. District Court E.D. Pa., Master Docket No. 2460

American Vanguard Corporation v. United States of America, U.S. Court of Federal Claims, Civil Action No: 16-194 C

In re Lamictal Direct Purchaser Antitrust Litigation, U.S. District Court NJ, Case No. 12-cv-995 (WHW)

In re Thalomid and Revlimid Antitrust Litigation, U.S. District Court NJ, Case No. 2:14-cv-06997 (MCA) (MAH)

Celexa and Lexapro Marketing and Sales Practices Litigation, Kissiovski et al. v. Forest Pharmaceuticals et al., MDL No. 2067 Master Docket No. 09-MD-2067-(NMG) Case No. 13-CV-13113 (NMG)

Celexa and Lexapro Marketing and Sales Practices Litigation, PAINTERS AND ALLIED TRADES DISTRICT COUNCIL 82 HEALTH CARE FUND v. Forest Pharmaceuticals et al., MDL No. 2067 Master Docket No. 09-MD-2067-(NMG) Case No. 13-CV-13113 (NMG)

In re: Lidoderm Antitrust Litigation, MDL Docket No. 14-md-02521-WHO.

Cipro Cases I & II, JCCP Proceeding Nos.: 4154 & 4220, (Sup. Ct. Ca., San Diego County).

Plumbers' Local Union no. 690 v. TAP Pharmaceutical Products, Inc., et al.
Superior Court of New Jersey, Law Division: Monmouth County; Civil Action No. MON-L-3136-06.

Foster v. Chattem, Inc., U.S. District Court, M.D. FL, Civ. Case No. 6:14-cv-346-Orl-18GJK

Sandhaus v. Bayer AG et al., Tenth Judicial District Court, Johnson County, KS, Case No. 00-CV-6193.

People of the State of Illinois v. Abbott Laboratories et al. Circuit Court, Cook County IL No: 05 CH 2474.

In Re: Skelaxin (metaxalone) Antitrust Litigation, U.S. District Court, E.D. Tenn.,
Lead Case No. 2:12-cv-4, MDL 2343.

Jabo's Pharmacy, Inc. v. King Pharmaceuticals, Inc., No. 31,973 (Circuit Court,
Cocke County, Tenn.).

APPENDIX C

Materials Considered

Case/Court Documents

1. Class Plaintiffs' Memorandum of Law in Support of Motion for Class Certification
2. Class Plaintiffs' Opposition to The Declaration of Samuel Kadosh In Support Non-Parties' Anthem, Inc., Anthem Insurance companies, Inc., And Amerigroup Corp's Cross-Motion For Costs and Fees Pursuant To FRCP 45(d)(2)(B)
3. Deposition of Teia Amell, June 5, 2018
4. Deposition of Mario Bulding, August 8, 2018
5. Deposition of Kenneth Evans, May 25, 2018
6. Deposition of Suzanne Harwood, August 3, 2018
7. Deposition of Lesley Huston, August 10, 2018
8. Deposition of Landon Ipson, August 7, 2018
9. Deposition of Deborah Kronberg, October 19, 2018
10. Deposition of Barbara Minton, October 30, 2018
11. Deposition of Macy Shia, November 9, 2018
12. Deposition of Bethanie Stein, October 11, 2018
13. Deposition of Annette Sutorik, July 10, 2018
14. Deposition of Donna Wemple, August 10, 2018
15. In re: EpiPen (Epinephrine Injection, USP) Marketing, Sales Practices, and Antitrust Litigation, Consolidated Class Action Complaint, October 17, 2017
16. In re: EpiPen (Epinephrine Injection, USP) Marketing, Sales Practices, and Antitrust Litigation, Memorandum of Law in Support of Motion for Class Certification, December 7, 2018
17. In Re: EpiPen (Epinephrine Injection, USP) Marketing, Sales Practices and Antitrust Litigation, Memorandum and Order, February 28, 2019
18. Local 282 Agreement and Declaration of Trust, Art. II, Sec. 3; "Board of Trustees," teamsters Union Local 282 (last visited Mar. 14, 2019), available at <http://www.teamsterslocal282.com/benefits/board-of-trustees.html>.
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Books/Articles/Industry Publications

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